ORGAN TRANSPLANTS

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
INVESTIGATIONS AND OVERSIGHT

OF THE

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SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

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ORGAN TRANSPLANTS

WEDNESDAY, APRIL 13, 1983

House of Representatives,
Committee on Science and Technology,
Subcommittee on Investigations and Oversight,
Washington, D.C.

The subcommittee met, pursuant to call, at 10 a.m., in room 2325, Rayburn House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Mr. Gore. The subcommittee will come to order.

I would like to welcome all of our witnesses and guests.

This morning the subcommittee begins 3 days of hearings to evaluate the problems in obtaining organs for transplant surgery. Each of us has been moved by the stories of families seeking lifesavings organs for their critically ill loved ones. And no sooner has one family's plight been resolved, when it seems as if another, and then another, comes forth to stand in their place.

I am sure that many of you have wondered, as I have, why there isn't some system to help meet these compelling needs in a more rational way. Certainly there has to be a better way than relying on bursts of media publicity during what is an emotionally difficult time for the patient's family. It was for this very reason, especially after I was personally contacted to assist in such a search, that I directed the subcommittee staff to conduct the investigation which has brought us here today.

It will no doubt come as a surprise to many of us here that some organ procurement systems are already in place. These systems were initially developed by local surgical teams to find transplantable kidneys. In many cases, these local agencies were poorly equipped to answer the increasing demands for kidneys and, more recently, demands for other organs brought about by the great strides in transplant surgery. We will hear this morning from some of these organ procurement agencies who have struggled valiantly to fill a constantly increasing demand for transplantable organs, and from a most eminent panel of surgical pioneers who will describe the advances in this life-saving area of science.

The irony of the problem facing us, as we look at the present shortage of available transplantable organs, is that we have a shortage of organs in the face of plenty. Let me cite some figures to illustrate. At present, approximately 5,000 kidneys are being transplanted annually. Five thousands patients who are suitable candidates for kidney transplants are currently maintained on lifesaving dialysis waiting for a suitable kidney. The potential life quality improvements for these patients from successful transplant surgery and the cost savings potential are enormous.

A similar situaton exists for liver transplants. Dr. Starzl—from whom we will hear shortly—and his group at the University of Pittsburgh have performed 111 liver transplants in the 2-year period ending in January. Let me correct that and make it 112 because Dr. Starzl has been up all night transplanting yet another liver, and comes to this hearing room from the operating room. During this same time span, another 54 patients died while waiting for a donor liver.

Artificial hearts may, in time, provide hope for those thousands who could benefit from a heart transplant—currently there are 100 heart transplants per year—but development of artificial livers, kidneys, and organs of similar complexity are many, many years away.

An estimated 20,000 Americans will die this year from head injuries, brain tumors, and other circumstances that leave organs usable for transplantation. Only a small percentage of those people actually donate their organs, even though a Gallup poll taken some years ago indicated that 70 percent of all Americans were willing to have their organs donated for transplantation at the time of death.

Relatively few people actually sign a donor card or some other designated document for organ donation. In Maryland, for example, where the donor card is placed on the back of the driver's license, a recent survey showed that only 1.5 percent participated. Nationally, what is the net result of this disparity between professed intention and actual action by potential donors? Figures from a Center for Disease Control study—which we will also hear about today—found that 2 percent of the patients who die in American hospitals could be considered suitable donors, yet organs are actually being obtained from less than one-fifth of those potential donors.

Testimony during the next 2 days—and then on the third day, April 27—will describe the efforts of those who toil in this field. We will be hearing from experts in organ procurement and donor solicitation efforts, as well as from some of the families who have had direct experience with the system. We will also hear testimony from expert witnesses who will discuss the bioethical and legal issues involved. On the third and final day, we will hear from the Department of Health and Human Services and from a variety of witnesses who will suggest changes to improve the present systems.

I am extremely hopeful that these hearings will provide a focal point for improvements in the process and procedures for obtaining organs for transplantation so that families will no longer feel compelled to mount a solitary nationwide campaign.

I want to call on my colleagues for opening statements, but let me note first that we are going to have a change in the sequence of the panels. Panel 2 is going to come first—Mrs. Billie Hall with her son, Brandon, age 13 months; Dr. James Williams, associate professor of surgery at the University of Tennessee, Memphis; Mr. Gary Hall, transplant coordinator at the University of Tennessee, Memphis; and Capt. John H. Broderick, and Mrs. John Broderick, with their daughter, Adriane, age 28 months from Minden, La.

The reason for the change is good news, happy news. The long-awaited donor for Brandon Hall was located at 7 a.m. this morning. Mrs. Hall and her son will be flying back to Tennessee, along with Dr. Williams and Gary Hall, for surgery this afternoon. It is a very happy announcement. We are delighted you can be here with us for a short time before you have to go. We are going to change the panels for that reason.

Let me call on the ranking minority member of this subcommittee, Mr. Skeen.

Mr. SKEEN. Thank you very much, Mr. Chairman.

The 3 days of hearings beginning today take the subcommittee into one of the most impressive areas of recent scientific breakthroughs. Nowhere is the human drama surrounding science greater than it is for organ transplants. The fate of waiting organ recipients, hoping that somewhere in the United States someone with matched organ characteristics has had the vision and the charity to provide for the donation of their organs after death, is always a poignant story.

I know, because my niece, who will be testifying tomorrow, has recently undergone kidney transplant surgery after 3 years of biweekly dialysis treatments. I know the pain and trauma of adjusting to a lifestyle completely dependent on a machine. I am learning now, 2 months after Michelle's surgery, how the recent breakthrough in transplant technology can make a bright and hopeful new life from one burdened with debilitating medical treatments or death.

Let me congratulate and express my gratitude to those members of the medical community with us during our hearings for bringing us to the point we are today. It seems such a short time ago that I lost my sister to glomerulonephritis. She died in 1962; she was 28 years old. There were no options then, despite the best attention of the medical profession. There simply wasn't anything they could do.

The situation is illustrative of the rate or pace of change currently underway in the scientific community. We are seeing it more and more on this committee as major breakthroughs occur almost every day. In less than two generations, we have progressed from a situation where someone such as my sister was left with no option but death, to the situation today where my niece, Michelle, has the option of life either by machine or by transplant surgery. Certainly there is a lot to be grateful for, and much more to look forward to.

The key to what some observers are referring to as a Renaissance in transplant surgery is the drug cyclosporine. First used in Great Britain in 1978, this drug fights the body's rejection of transplanted organs, thereby improving the 1-year survival rate. The chances for successful transplants for such organs as heart, lung, kidney, and liver have more than doubled in the last 5 years.

With the improvements in surgical techniques and new drugs, over 5,000 people benefited from organ transplants in 1981. The number is growing all the time, and more organ recipients are experiencing successful transplants. The future of this field of research is, in my opinion, without limit. A decade from now, we will find a medical community capable of major feats of not only transplanting organs, but of reconstructing damaged ones as well. The benefits to many Americans will be truly astounding.

Our subcommittee applauds all of our witnesses, doctors, and patients alike, and we welcome you to Washington. We also bid you farewell if you need to get out of here for that transplant today, and we appreciate your time that you have given us. It is my hope that we might be able to listen to you in these 3 days and find some way to help this process along. Most of the networking for organ donors and recipients has been from the ground up, and the support organizations you now have are very impressive. If you think the Federal Government can help, I would like to hear about it. Under the leadership of our chairman, Mr. Gore, I am confident that the subcommittee will take the necessary and proper steps to aid in this progress.

Thank you, Mr. Chairman.

Mr. GORE. Thank you very much.

Congressman Scheuer has an opening statement.

Mr. SCHEUER. Thank you, Mr. Chairman. I will make it brief. I know we are all eager to get to the witnesses.

We are at a wonderful point in time. I want to thank you for your leadership in bringing us all together. These transplants that were once unthinkable are now a practical therapeutic alternative to such expensive and life debilitating procedures as renal dialysis. Now the transplant technology is here to stay, thanks to the drug cyclosporine that has apparently solved the rejection problems.

We in Congress must evaluate and analyze how the Federal Government can aid in organ procurement and how we can make sure that every patient who needs an organ for a transplant has one. We must also examine the adequacy of the medicare coverage for transplants, both in terms of the procedures and the length of time that the benefits are available.

In no way should the Federal reimbursement mechanism act as a disincentive to transplants which are far more live-saving, far more live-enhancing, and far cost effective than conventional therapies.

Let me congratulate you again on scheduling this remarkable hearing, Mr. Chairman.

Mr. GORE. Thank you very much.

Congresswoman Schneider.

Mrs. SCHNEIDER. I would like to thank you, Mr. Chairman, for organizing and pulling together what I think is a very timely and interesting hearing. I think all we need to do is to look at the newspapers or turn on the television set and see the remarkable advances that have occurred in the area of organ transplants.

The thought of vital organs, such as livers, hearts, and kidneys, being transplanted routinely at our Nation's best medical centers is a tribute to how far transplant technology has evolved since its earliest days a decade and a half ago. The works of Doctors Shumway, Starzl, and Williams—to name some of the leaders—combined with the R&D of the pharmaceutical industry in perfecting a powerful, yet safe and practical drug, cyclosporine, demonstrates great hope and promise of modern medicine.

Now that the medical technology is so very advanced, we have to make certain that its support system in terms of organ procurement keeps pace. One of the witnesses later today, I am proud to say, is from my State of Rhode Island, and very actively involved in helping connect the supply with demand. I think it would certainly be a tragedy if, after realizing that we have the technological breakthrough medically and pharmaceutically, that we don't take full advantage by affording this remarkable therapy to all needy patients.

I feel certain that, through the work of the subcommittee and elsewhere in Congress, we can have a very meaningful impact on the availability of transplant surgery, and I look forward to the testimony of our distinguished witnesses at this morning's hearing.

Thank you very much.

Mr. Gore. Thank you very much.

Mrs. Hall, if you and Brandon could come to the witness table. We are delighted to have you here. Captain Broderick, I would like you and Adriane to join them at the center of the table there. Dr. Williams, you are already at the witness table. Mr. Hall, if you could join us as well.

By way of introduction, let me say that Mrs. Billie Hall lives in Walnut, Miss., with her son, Brandon, age 13 months. Brandon has been awaiting a liver transplant for quite a long time now. As I mentioned before, there was happy news just this morning which will take Mrs. Hall and Dr. Williams and Mr. Gary Hall back to Tennessee.

Capt. John Broderick and his daughter, Adriane, age 28 months, live in Minden, La. They are also patients at the UT Health Center with Dr. Williams, who is joining us. We also have Gary Hall, who is the transplant coordinator at the University of Tennessee.

To introduce our Tennessee witnesses, I am honored to recognize our distinguished colleague, Congressman Harold Ford.

STATEMENT OF HON. HAROLD E. FORD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mr. Ford. Thank you very much, Mr. Chairman and other members of the subcommittee, for your kind words and for granting me the opportunity to introduce two distinguished professionals from the great State of Tennessee and from my district at the Medical Center.

Before I continue my introduction of our Tennessee guests, let me say that I, too, am cognizant of the fact that there are problems related to the organ procurement for transplants. Not long ago, my office in Memphis, Tenn., was contacted by our local media to help in the search for a liver donor for a child hospitalized in my district. I was shocked and dismayed to learn that a media campaign of that magnitude had to be launched in order to procure a suitable donor.

I commend both Chairman Gore and the Committee on Science and Technology for this hearing today and for this subcommittee taking the time out of its busy schedule to arouse the awareness from the congressional standpoint, as well as public awareness, of the problems associated with organ procurement for transplants.

The University of Tennessee's Center for Health Sciences has made a giant stride in the science of organ transplants. It is one of the three major centers engaged in liver transplants, and the only designated kidney transplant center in west Tennessee. Since May 19, 1982, when the center conducted its first liver transplant, seven other transplants have been successful in that medical center.

It is my distinct pleasure to introduce Dr. James W. Williams, who heads the surgical team at the University of Tennessee that has performed five liver transplants since last May; and Mr. Gary Hall, the university's transplant coordinator. Without the invaluable services and knowledge of these two professionals, much of the progress that we have made in our hometown would not be there. We are proud today to have the two before this subcommittee in the Congress.

Once again, let me say that it is my sincere pleasure to introduce them, and to know that we do have a donor as of 7 o'clock this morning for the son of Mrs. Hall.

Thank you, Mr. Chairman and the members of this subcommittee.

Mr. GORE. Thank you very much, Congressman.

We want to hear first from Mrs. Billie Hall. Mrs. Hall, I know this is a dramatic day for you. It is our hope, as I know it is yours, that the experience you have been through will be of some benefit to others who will be undergoing the same challenge of finding a donor for a child who needs an organ to live. We are delighted to have you here on this special day. If you could share some thoughts with us, we would appreciate it.

STATEMENTS OF BILLIE HALL, WITH SON, BRANDON HALL; CAPT. JOHN H. BRODERICK, WITH DAUGHTER, ADRIANE; JAMES WILLIAMS, M.D., ASSOCIATE PROFESSOR OF SURGERY, UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE, MEMPHIS, TENN.; AND GARY HALL, TRANSPLANT COORDINATOR, UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE, MEMPHIS, TENN.

Mrs. BILLIE HALL. Thank you very much for having us. I thank you not only for Brandon, but for everybody else who is here with children that have Brandon's problems.

I would like to tell you a few things that happened to Brandon over the last 13 months. Brandon was 2 weeks old when we found out that he has biliary atresia. He had surgery at that time, and they were hoping that the surgery that they did would correct the problem long enough, at least until he could get big enough for a transplant.

He did fine for 3 or 4 months, and then he started having bleeding problems around his stomach. Dr. Whittington, Brandon's doctor, told me that to live, Brandon would have to have a transplant. He told us that we would have to have so much money to get Brandon in the hospital. Brandon has SSI, and I don't have any insurance. He told me that medicaid would not pay. So, we were faced with another problem. We had to get at least $30,000 together to get Brandon in the hospital.

We have a small religious radio station in Walnut, and they got behind us, and we worked for 5 months and raised $81,000. We were fortunate. God was with us. There are so many people who won't be as fortunate as we have been. There needs to be something done about the medicaid helping these children. It is so terrible to see a child die because they do not have the money to pay for getting help for their child. We did raise the money.

In December, Brandon started losing weight. He was going down every day. They were afraid they were going to have to put him on the list for a donor then. But we started feeding him with NG-2 and he gained weight back up to 19 pounds. We thought we were in good shape then, but he started retaining fluid. He just started doing real bad.

I am sorry.

Mr. **Gore**. That is all right.

Mrs. **Billie Hall**. This is a good day.

Mr. **Gore**. It is an emotional day. We understand.

Mrs. **Billie Hall**. Brandon's birthday was in March. The week after his birthday, Dr. Williams and Dr. Whittington put Brandon on the search list for a liver. They thought at that time that he had 1 month or maybe 2 months before he would need the donor. So, they weren't pushing it. They just had him on the search list.

A couple of weeks ago, Brandon started retaining fluid again and running a fever and just having several recurring things happening to him, like the fluid and everything. So, they put him on the rush list. They put him on top priority for a donor.

Thank God, this morning we did get one. We are one of the very few that are so fortunate to find a donor. There needs to be so much more public awareness. Until people know the need for these children, we are going to have these problems. We have had so many people behind us, so we are very fortunate. You can look around. There are so many people here with children just like Brandon that needs the surgery just as bad as my son does.

If there is anything that can be done to help to make more public awareness or get a better system set up, we do need it. They need it. We have got ours. With God's help, we are going to make it. But there are so many here who might now. So, please, if there is anything that you can do to help these others, we would appreciate it so much.

Thank you.

Mr. **Gore**. Thank you, Mrs. Hall.

When these hearings were announced, we found that a lot of people came with children who we didn't expect to come. But there are a number of mothers and fathers with children who came to these hearings for precisely the reasons you just outlined.

Our next witness is the father of a young child, Adriane, age 28 months, who is awaiting a transplant. Captain Broderick, we all wish that you and your family could share in the joy that Mrs. Hall feels this morning. The sharp disparity between the two experiences you all are having today points up again the need for a nationwide rational system to help families in this distress out. So, we would be delighted to hear from you, Captain Broderick.

Captain **Broderick**. Thank you.

I have a short statement.

Mr. **Gore**. Captain Broderick, let me say for the record that you are a captain on active duty in the U.S. Army; is that correct?

Captain **Broderick**. Yes, sir.

Mr. **Gore**. You are stationed where?

Captain **Broderick**. Louisiana Army Ammunition Plant.

Mr. **Gore**. Thank you very much. Please proceed.

Captain **Broderick**. Our daughter, Adriane is now 28 months old and has biliary atresia. She was born November 30, 1980, in Athens, Greece. She also exhibited jaundice on birth. Unfortunately, because of the environment we were in, it was not discovered as quickly as Brandon's. She was flown to a military hospital in Germany where the possibility of biliary atresia was diagnosed. Her military physicians at that time were not very optimistic regarding her survival, and indicated she would probably die within several months without major surgery.

She was then transferred to Walter Reed Army Medical Center where additional tests confirmed the diagnosis of biliary atresia. Since the Army medical system at that time could not perform the corrective surgery, she was transferred to Children's Hospital National Medical Center in Washington, D.C., in February 1981.

There it was decided a Kasai procedure would be necessary in order to find bile ducts large enough to prevent her liver from dysfunctioning and allow bile flow. At that time, she only had a 50-percent chance of success. The operation was performed by Dr. Kathryn Anderson. After some complications, she responded to the surgery and was released in March 1981.

I was then stationed in Alabama, and her condition again began to deteriorate in April. As a result, she was admitted to Vanderbilt University Medical Center in May. Dr. Wallace Neblett revised the original Kasai procedure, but the advancing cirrhosis she developed made the operation very difficult. Her prognosis upon release was poor. It was felt her liver would fail, and she would die within a year.

She suffered increased bleeding from a portoenterostomy in June, and was again readmitted to Vanderbilt for additional surgery in February 1982.

After she was released, she was followed by numerous military and civilian physicians in an attempt to stabilize or delay the advancing deterioration of her liver.

In August 1982, after examination by Dr. John Andersen of the University of Texas Health Science Center at Dallas, the possibility of a liver transplant was discussed as the only way to save her life.

We then traveled to the University of Tennessee Center for the Health Sciences in Memphis. At that time it was one of the few centers doing transplants. Dr. James W. Williams confirmed her prognosis, and suggested Adriane would be an ideal candidate for a liver transplant. After a long period of hopelessness, watching her slowly die from this disease, a transplant gave us our first hope for her continued survival.

Little did we know that her continually deteriorating medical condition and the difficulty in finding a suitable organ for transplantation were not the only obstacles to overcome in saving her life.

As an active-duty member of the Armed Forces, CHAMPUS [Civilian Health and Medical Program for the Uniformed Services] is responsible for providing medical care for my family if the normal military medical system cannot provide that care. After allowing coverage for three major operations, we were surprised to learn CHAMPUS would only pay for her to die in a hospital and not for the liver transplant which would save her life. If at any point a transplant was necessary, I was personally responsible for the bills.

Since $65,000 is the cost of admittance for the hospital doing the transplant, my only available means of getting the necessary funds to save my daughter's life would be public fundraising or medicaid. Further investigation revealed three reasons why my daughter's medical condition was disallowed by CHAMPUS.

The first is, since there are a limited number of centers who are actively doing the procedure, liver transplantation cannot be readily replicated, nor be provided with a predicted level of success at a significant number of facilities and, therefore, it does not meet the generally accepted standards of usual professional medical practice in the general medical community.

The question as to whether this procedure is routine is not for me to answer, but I assume the testimony the physicians from the various centers will give will adequately demonstrate that liver transplantation is an accepted standard of usual professional medical practice for treatment of severe liver dysfunction.

The second consideration is that other federally funded health programs, as well as other third-party payers also consider the procedure to be investigational.

Based upon my research and the research of others, this is based upon an outdated National Institutes of Health survey conducted in October 1980, which states the liver transplant success rate is approximately 38 percent. This survey was prior to the use of cyclosporine A, and only mentions cyclosporine A as being used in limited human trials, specifically Dr. Starzl's work. The success rate is obviously higher. As far as other federally funded health programs, I have received limited Massachusetts medicaid coverage because of Senator Kennedy's personnel's efforts. And it is my understanding numerous States like New York and Pennsylvania consider liver transplants therapeutic.

From my own experience, the University of Tennessee has informed me the only major insurance carrier who has not provided coverage at that hospital is CHAMPUS.

The final consideration is the high cost of the procedure, typically $50,000 to $60,000, versus the expected long-range benefit to be derived. I, personally, find this argument repugnant, since it de facto has set a dollar value to my daughter's life. It would appear CHAMPUS is all too willing to pay for her to die, at a greater cost than for her to live. The expected long-range benefit is her life. If economics is the consideration, then the transplant is cost effective, a position reinforced by the Surgeon General of the United States.

There are three hurdles in my opinion that we have to overcome. The first is finding the funds to get your child into the hospital; the second—obviously Brandon has met that hurdle—is finding a liver; the third—typified by Jamie Fiske—is surviving the actual surgery.

Why is the reimbursement issue important to us? Without the funds to gain admittance, I cannot even achieve the first hurdle.

In conclusion, Adriane is still suffering from the debilitating effects of her biliary atresia, and ultimately she will succumb to liver failure, probably within 18 months. She does have hope for continued survival with a good quality of life if she receives a successful liver transplant. This, of course, is dependent upon our ability to afford the operation.

Your recommendations that liver transplantation is not investigational, combined with improved methods of organ procurement, and the legislation currently in Congress which allows widespread acceptance of the procedure, can save numerous lives from liver disease—possibly Adriane's.

That concludes my oral testimony, sir.

Mr. **Gore**. Captain Broderick, so I understand your testimony, before we complete the panel, CHAMPUS is the health plan provided by the U.S. Government to active-duty members of the military, and the U.S. Government, through CHAMPUS, has refused to pay for your daughter's liver transplant, in part because it would cost $50,000 to $60,000; is that correct?

Captain **Broderick**. Yes, sir.

Mr. **Gore**. We will certainly have some questions about that when the panel has concluded.

[The prepared statement of Captain Broderick follows:]

Our daughter, Adriane is now 28 months old and has biliary atresia. She was born November 30, 1980 in Athens, Greece. Her jaundice on birth did not clear up after several weeks, and she was flown to a military hospital in Germany where the possibility of biliary atresia was diagnosed. Her military physicians were not optimistic regarding her survival, and indicated she would probably die within several months without major surgery.

Adriane was then transferred to Walter Reed Army Medical Center, where additional tests confirmed the diagnosis of biliary atresia. Since the Army medical system could not perform corrective srugery, she was transferred to Children's Hospital, National Medical Center in Washington, DC, in February 1981.

There it was decided a KASAI procedure would be necessary in order to find bile ducts large enough to permit bile flow from the liver.

With only a 50% chance of success, the operation was performed by Dr. Kathryn Anderson. After some complications, she responded to the surgery and was released in March 1981.

Then stationed in Alabama, her condition began to again deteriorate in April. As a result, she was admitted to Vanderbelt University Medical Center in May. Dr. Wallace Neblett revised the original KASAI procedure, but the advancing cirrhosis she developed made the operation difficult. Her prognosis upon release was poor - it was felt her liver would fail, and she would die within a year.

She suffered increased bleeding from a portoenterostomy in June, and was again readmitted to Vanderbelt for additional surgery.

After she was released, she was followed by numerous military and civilian physicians in an attempt to stabilize or delay the advancing deterroration of her liver.

In August, 1982, after examination by Dr. John Andersen of the University of Texas Health Science Center at Dallas, the possibility of a liver transplant was discussed as the only way to save her life.

We then travelled to the University of Tennessee Center for the Health Sciences in Memphis, one of the few centers doing transplants. Dr. James W. Williams confirmed her prognosis, and suggested Adriane would be an ideal candidate for a transplant. After a long period of hopelessness, watching her slowly die, a transplant gave us our first hope for her continued survival.

Little did we know that her continually deteriorating medical condition and the difficulty in finding a suitable organ for transplantation were not the only obstacles to overcome in saving her life.

As an active-duty member of the armed forces, CHAMPUS is responsible for providing medical care for my family if the normal military medical system cannot provide certain care.

After allowing coverage for three major operations, we were surprised to learn CHAMPUS would only pay for her to die in a hospital and not for the liver transplant which would save her life. If at any point a transplant was necessary, I was on my own for the bills.

Since $65,000 is the cost of admittance for the hospital doing the transplant, my only available means of getting the necessary funds to save my daughter's life would be public funding raising or Medicaid. Further investigation revealed three reasons why my daughter's medical condition was disallowed by CHAMPUS.

The first is since there are a limited number of centers who are actively doing the procedure, liver transplantation cannot be readily replicated nor be provided with a predicted level of success at a significant number of facilities, it does not meet the generally accepted standards of usual professional medical practice in the general medical community.

The question as to whether this procedure is routine is not for me to answer, but I assume the testimony the physicians from the various centers have given adequately demonstrate that liver transplantation is an accepted standard of usual medical practice for treatment of severe liver dysfunctions.

The second consideration is that "other federally funded health programs, as well as other third-party payors also consider the procedure to be investigational."

This is based upon an outdated NIH survey conducted in October of 1980 which states the liver transplant success rate is approximately 38%. This survey was prior to the use of Cyclosporin A, and only mentions Cyclosporin A as being used in limited human trials. The success rate is obviously higher. As far as other federally funded health programs, I have received limited Massachusetts Medicaid coverage because of Senator Kennedy's efforts, and it is my understanding numerous states like New York and Pennsylvania consider liver transplants therapeutic. From my own experience, the University of Tennessee has informed me the only major insurance carrier who has not provided coverage at that hospital is CHAMPUS.

The final consideration is "the high cost of the procedure, typically $50,000 - 60,000, versus the expected long-range benefit to be derived." I personally find this argument repugnant since it defacto has set a dollar-value to my daughter's life. It would appear CHAMPUS is all too willing to pay for her to die, at a greater cost, than for her to live. The expected long-range benefit is her life. If economics is the consideration, then the transplant is "cost-effective," a position reinforced by the Surgeon General of the US.

Why is the reimbursement issue important - without the funds to gain admittance, improved procedures for liver procurement are unnecessary.

In conclusion, Adriane is still suffering from the debilitating effects of her biliary atresia, and ultimately she will succumb to liver failure, probably within 18 months.

She does have hope for continued survival with a good quality of life if she receives a successful liver transplant. This of course is dependent on our ability to afford the operation.

Your recommendations that liver transplantation is not investigational, with improved methods of organ procurement, and the legislation currently in Congress which allows wide-spread acceptance of the procedure, can save numerous lives from liver disease - possibly Adrianes'.

That concludes my oral testimony.

BIOGRAPHICAL SKETCH

JOHN M. BRODERICK

CAPTAIN, UNITED STATES ARMY

John M. Broderick, III, was born in Ft Dix, NJ, on 30 May 1956. He graduated from High School in Bellingham, Massachusetts. He earned a Bachelor of Arts Degree from Providence College in 1978.

He began his active duty career in June 1978 as a Second Lieutenant in the Ordnance Corps, and graduated from the Ordnance Officer's Basic Course (phase II - nuclear) as Distinguished Graduate.

From February 1979 to April 1982, he served in the 558th USAAG, Greece. In April 1982, he returned to Redstone Arsenal, Alabama, and was assigned to the 515th Ordnance Co.

In 1983, he graduated as the Honor Graduate, Ordnance Officer Advanced Course. He is presently assigned to the Louisiana Army Ammunition Plant, Shreveport, Louisiana.

Personal Data

Born: 30 May 1956 - Ft Dix, NJ
SSN: 014-48-5891
Parents: John M. and Sara P. Broderick, Jr.
Wife: Janet M. Broderick
Children: Adriane Marie Broderick

Home Address

19 Colin P. Kelly Drive
Minden, Louisiana 71055

Phone: (318)459-5309

Mr. **Gore**. Our next witness is Dr. James Williams, associate professor of surgery at the University of Tennessee College of Medicine. Dr. Williams, we are honored to have you with us today. Please proceed with your testimony.

Dr. **James Williams**. Mr. Chairman and members, thank you for allowing us the opportunity to come to Washington and speak with you on this issue we consider to be very important to the health of a growing number of Americans.

I want to personally express my thanks to Mrs. Hall for her herculean efforts to come here, and her almost unbelievable composure on her day of days, regardless of the outcome.

The development of liver transplantation at the University of Tennessee Center for the Health Sciences is outlined in my written testimony.

In summary, we initiated our liver transplant program in May 1982, a project based on extensive laboratory and clinical preparation. Since that time, a little less than a year now, we have performed a total of seven transplants, three of the patients have been discharged home, and two other patients, recently done, are awaiting discharge.

This very gratifying start illustrates the concept that liver transplantation can be performed successfully by more than a few select centers. Several other centers are now organizing liver transplant programs. Given adequate preparation, these programs will prove similary successful and dispell the myth that liver transplantation is merely a clinical experiment.

As a new liver transplant program, we face two major problems. The first problem, encountered by approximately half the patients referred to us, is the lack of financial support for the procedure. All Federal agencies, including CHAMPUS and medicare, and many private insurance carriers refuse to cover the procedure because of its experimental status.

The second problem we have encountered is the frequent difficulty in finding a liver donor, particularly for a small child. Since the child with end-stage liver disease has a relatively short period of time to live, and since the donated liver is viable for a only a short time once it is removed from the cadaveric donor, and since the number of pediatric donors itself is small, the urgency of the need for a donor can literally reach life and death magnitude. The witnesses here today, Brandon and Mrs. Hall, as well as Adriane Broderick, illustrate these two problems as graphically as they could possibly be illustrated.

Mrs. Hall, confronted with a fatal illness in her child, has been able to raise the necessary money and assure her son's admission to a transplant center. Several other patients we have seen, however, in this same situation, have not been so successful and have since succumbed.

What can be done at a national level to assist in solving these problems? I don't have any magic solutions, but I have a few suggestions for your consideration. One, in the area of donor availability, public awareness and public understanding of the problems involved is important—is probably the most important thing we can pursue at this stage. The general public, I don't believe, realizes the seriousness of the problem, nor the precious quality of this resource, donated solid organs. Organ donation always comes at a tragic time. It is not a time when the family can think rationally. These decisions have to be made at a prior time. This is in the realm of public education, public relations, ways of educating the public.

A second route to take is in hospital involvement. There are a number of hospitals in this country in which organ donation occurs rarely, is rarely considered. In smaller hospitals, the knowledge for the need is not disseminated. I think we have to need to have a uniform policy in our hospitals about the approach to organ donation. If the intensive care unit nurses or someone designated within those units were given the opportunity or the job or the responsibility for doing this to everyone, presenting the opportunity for organ donation for every family with a relative or member of their family dying, I think we would see increased availability of organs. This would ritualize the process, defuse some of the emotionalism, and make it a regular part of the care of this type of person.

In the area of funding, I would encourage us to make some steps toward assuring uniformity in our hospital insurance carriers. A number of carriers have, in my opinion, hidden behind the term "experimental." This term is too vague in a time of inovation, when new things are happening all of the time. If we excluded payment on the basis of experimental or newness, we would never do anything new, we would never make any advances. So that needs to be defined.

For those who do not have insurance—which probably represents a large segment of children, because children happen to be the dependents of young working people, many time changing jobs and changing insurance companies, and a new insurance company may not pick up the tab for a pre-existing illness—we still have a number of people who don't have coverage at all. We could consider doing these transplants with funding through the clinical research center system.

I don't know how much money that would take, but it would accomplish three things. One, it would take care of the patients who need a liver transplant in this country. Second, it would improve the research and developmental support that we all agree is needed. Third, it would do this without creating any new laws, without creating any new bureaucracy, and without committing funds for an indefinite period of time. This would be research-related money.

I appreciate the opportunity to come to Washington to testify, and I will be happy to answer questions should they arise. Thank you.

Mr. GORE. Thank you very much, Dr. Williams.

We will hold questions until Mr. Hall has had an opportunity to testify.

[The prepared statement of Dr. James Williams follows:]

LIVER TRANSPLANT PROGRAM AT THE UNIVERSITY OF TENNESSEE CENTER FOR THE HEALTH SCIENCES

The liver transplant program at the University of Tennessee began in May of 1982, becoming the third active program in this country and the first program to become organized in the Cyclosporine era. This program has evolved in a major university setting and draws extensively from the expertise of physicians and technicians in a wide variety of medical and scientific disciplines. This broad background of support is extremely valuable, since the problems encountered with patients in end-stage liver disease can be both numerous and complex. Having accounted for this broad support, I would like to concentrate this testimony on the development of the surgical aspects of this program, and the problems encountered by the family of a small child needing a liver transplant.

A kidney transplant program at the University of Tennessee began in 1970 and has been responsible for the development of an active organ retrieval effort, as well as the performance of approximately 350 renal transplants. This effort, based on the treatment and follow-up of patients receiving kidney transplants, has provided the liver program with considerable experience in transplantation biology and the management of immunosuppressed patients.

The author's interest in transplantation began in 1978, when he spent six weeks at the University of Colorado observing the program under the direction of Thomas Starzl, M. D. Fortified by the belief that a similar program could be initiated elsewhere, we began preparations for a liver program at the University of South Florida in Tampa. When it became apparent that this could not be accomplished in that institution, the University of Tennessee accepted our offer to start a program in Memphis.

Preparation for this program included recruitment of two skillful surgeons experienced in kidney transplantation and general surgery. Over a two year period, these surgeons and I carefully dissected the liver in several cadavers in order to become familiar with the frequent variations in liver anatomy and the technical aspects of multi organ retrieval. During and preceding this two year period, we conducted a series of canine liver transplant experiments, investigating the use of Cyclosporine. In addition to the experimental data generated, these experiments provided valuable technical experience in liver preservation and in the actual performance of the transplant operation, which has been heavily drawn upon in the subsequent clinical series.

Based on this laboratory and clinical preparation we began our program and performed the first liver transplant in May of 1982, using Cyclosporine as the mainstay of immunosuppression. In the nine months since that time we have transplanted seven patients, three of whom have been discharged home and two are awaiting discharge. We currently have two patients with end-stage liver disease awaiting a suitable donor.

The results of our program support the concept that hepatic transplantation is a procedure of genuine therapeutic benefit. The patients selected for transplantation at our institution have had end-stage liver disease and were expected to live only a few weeks or months. The experience from our institution indicates that, with careful preparation, a new program can provide liver transplantation therapy in a safe and efficacious manner. Enough details of the surgery and care of the patients are known so that duplication of these results should be expected at other similar institutions.

It is, therefore, our opinion that liver transplantation should no longer be considered experimental. This designation, used by several Federal and private health care providers, denies transplantation to approximately one-half of the patients referred to us with end-stage liver disease.

The child appearing before your committee, Brandon Hall, is a one year old boy with a disease called biliary atresia. This is a condition, present from infancy, in which the bile ducts normally connecting the liver to the intestine are absent. Since bile is denied entry into the intestine, the child becomes jaundiced and the liver experiences progressive scarring and progressive loss of function. Symptoms of this disease include itching, increased susceptibility to infection, fluid retention, vitamin malabsorption, bleeding problems, growth failure and others. This condition occurs approximately in one in every 8,000 to 12,000 births and proves fatal in the majority of affected children before the age of 3 years. Therapy for this condition includes both surgical attempt at bile drainage (helpful in a small number of children) and the treatment of symptoms produced by the obstructed bile flow. Since the liver is progressively destroyed by this condition, the only hope for extended life is a successful liver transplant.

Liver transplantation is a complicated, lengthy and tedious procedure. The current evidence suggests that it can be successful in up to 60% to 70% of the patients.

Liver transplantation in children is complicated by two features. The first feature is the relative scarcity of suitable donors for children. The second feature is the disproportionately high incidence of clotting of the artery supplying small livers in these children. This is a fatal complication unless another liver can be quickly found.

Last year Brandon's mother, Mrs. Billie Hall, was told that her six month old son could not survive without a liver transplant. In addition to the uncertainties regarding the future of her child, she was also told that financing was a major problem. Since she had no insurance and the medical care she had been receiving was afforded by Medicaid, she was told that her child could not have a transplant unless she could raise the money herself. In an all out appeal, Mrs. Hall was able to raise approximately $75,000.00, and thereby, provide her son with access to this therapy. When we saw the child for the first time, he weighed approximately eleven pounds and appeared to be in poor condition. Through the therapy initiated by Dr. Peter Whitington, Pediatric Gastroenterologist at LeBonheur Children's Hospital at the University of Tennessee Center for the Health Sciences, Brandon has been able to grow and gain weight. However, in the past few weeks his growth has stopped and complications related to a failing liver have appeared. He is becoming increasingly jaundiced, lethargic, and has constant fever of 101° to 102°.

Brandon Hall is now on the urgent list awaiting a new liver. Providing a liver can be found, we believe his chances for long-term, indefinite survival are good. Without the transplant he will live only a few weeks.

The future of liver transplantation will depend upon two broad areas of advance. The first area will be improvements in the control of rejection and improvements in the technical aspects of performing the surgery. This will require research support. The second area of advance will come from public awareness of the precious resource organ donation represents. Kidney and cornea transplantation has been performed for over two decades and has afforded thousands of people a richer and fuller life than otherwise possible.

In many cases successful kidney transplants have undoubtedly improved life expectancy as well, but an alternate form of life sustaining therapy (dialysis) is available to patients with kidney failure. On the other hand, there is no meaningful therapy short of transplantation for patients with end-stage liver failure. Since the patient with end-stage liver disease has a relatively short period of time to live, and since the donated liver is viable for only a short time, once it is removed from a cadaveric donor, new urgency is being progressively placed upon organ procurement. Based on vital statistics defining both the incidence of death from liver disease and the number of potential organ donors, it appears that the supply of needed livers can be readily met. Meeting this need, however, will come through public education and efforts such as this committee is promoting.

Thank you for the opportunity of appearing before your committee.

Yours truly,

James W. Williams, M. D.
Associate Professor of Surgery

JWW:lc

Mr. **Gore**. Mr. Gary Hall is the transplant coordinator with the University of Tennessee College of Medicine in Memphis. Welcome, Mr. Hall.

Mr. **Gary Hall**. Thank you, Congressman Gore, for the opportunity to appear this morning.

Mr. **Gore**. Congratulations on your success this morning, Mr. Hall.

Mr. **Gary Hall**. Thank you. That really is the success of the cooperative efforts that go on at all times among transplant coordinators in this country. It is not my success, it is our success.

I have been requested to relate the activities or our organ procurement program in locating suitable organs for transplantation. My specific remarks will outline my activities related to finding a suitable liver for a small pediatric recipient, such as Brandon Hall, and the general approach to organ procurement at the University of Tennessee.

Rarely are organ donors "found" by organ procurement coordinators; rather, organ donors are brought to the attention of coordinators as a result of a referral by health professionals not normally involved in organ procurement.

Locating a suitable liver for a small pediatric recipient—or really any recipient—involves a two-pronged effort: first of all, a local effort, an ongoing systems approach that will be described later; and two, a nationwide effort. This nationwide effort involves listing the patient, along with acceptable donor parameters, on a national telephone system called the North American Transplant Coordinators Organization 24-Alert phone system; 24-Alert is an acronym for the phone number of this system, and is accessible from any telephone in the world. Mr. Don Denny, director of organ procurement at the University of Pittsburgh which administers this system, will comment later during these hearings relative to the mechanics of that system.

In particularly urgent cases, such as the one involving Brandon Hall, various organ donor programs are directly contacted to make them aware of our need and requested not to reject infants as organ donors in contrast to the usual policy—infant kidneys are rarely needed for transplants. In these situations, our program accepts full fiscal responsibility for the organ retrieval procedure where there is considerable doubt as the transplantability of the donor's kidneys. To date, we have been successful in procuring a suitable organ for every eligible patient awaiting liver transplantation at our center.

Our local organ procurement program, similar to organ procurement programs in other areas, has been marginally successful in retrieving an adequate number of organs for transplant.

The various attachments to this testimony represent our efforts to develop an understanding of the inhibitions physicians and nurses in our community have toward participating in organ procurements. For a very long time now, organ procurement has been struggling to be universally recognized in our medical community as a valid and legitimate endeavor. Often those in authority in the hospitals in our area, upon which we rely for eligible organ donor referrals, either acquiesce or are apathetic to our requests to be permitted to educate and inform nurses and physicians working in hopital areas where organ donors are most likely to be found.

In contradistinction to the lack of uniform affirmative support for organ donation on the part of hospitals in our area, we have the definite impression that a majority of physicians and critical care unit nurses favor cadaveric organ donation. This impression is confirmed by positive responses to the survey questions concerning physicians' and nurses' attitudes toward personal organ donation—attachments one and four.

Despite these favorable attitudes, it is clear that a majority of donors are not identified and referred to the transplant program. Furthermore, it is the perception of most critical care nurses that a majority of eligible donors under their care are not identified nor are their families advised of their right to exercise the organ donor option—attachments two and four.

In attachment four can be found data suggesting that considerable uncertainty exists on the part of critical care nurses as to their hospital's position on organ donation. This fact further suggests possible contributing causes of the nurses' uncertainty about the identification of eligible organ donors.

Due to the lack of a uniform systems approach, organ procurement coordinators spend most of their time selling through in-service seminars and unscheduled visits to critical care units to acquaint critical care nurses with organ donation procedures. These sessions generally include an emotional appeal to the nurses to approach families of eligible organ donors or, at the very least, to contact the organ procurement coordinator and permit them to discuss donation with the potential donor's family.

The foregoing is not intended as an indictment of hospitals, physicians or nurses, nor is it intended to characterize them as apathetic toward the needs of patients awaiting transplantation. These institutions and professionals have some real and legitimate concerns about their participation in facilitating organ donation. These concerns may be summarized as follows:

One, the majority of organ donations occur in acute care hospitals not associated with organ transplant programs. Consequently, the focus of attention of these hospitals and staff is on aspects of patient care not related to transplantation. Organ donation does not directly benefit their patient population.

Second, there exists a general belief on the part of the physicians and nurses that organ donation does not enjoy widespread public support. That this notion has merit was confirmed in a public opinion survey conducted by the Gallup Organization earlier this year. This survey performed, for the National Kidney Foundation, found that only 40 percent of those polled—44 percent of white participants, and only 20 percent of black participants—indicated they were either very or somewhat likely to want their own kidneys donated after their death. Our experience in Memphis, where the proportion of blacks in the population approaches 50 percent, confirms the findings of the Gallup survey. Approximately 20 percent of black families approached about organ donation ultimately consent to it. This circumstance serves to discourage physicians and nurses treating a black patient who dies, and is otherwise suitable for organ donation, from approaching that patient's family.

Finally, a continued major concern is the issue of public acceptance of brain death as the death of the person. Most physicians and a majority of legislators accept the idea that an individual who has suffered irreversible cessation of total brain function, regardless of the continuance of function of other organ systems, is legally dead. The level of certainty among critical care nurses is somewhat less than that of physicians. It is not surprising, therefore, that a substantial proportion of families have difficulty accepting the explanation that one is dead when they feel a pulse and see them breathing, albeit that these processes are mechanically maintained. It requires a concerned, compassionate and committed physician and/or nurse to spend sufficient time with the family to help them understand that their relative is truly dead. Family acceptance of brain death of the individual is absolutely essential before a discussion of organ donation can ensue and be expected to result in consent for organ donation.

In conclusion, two things will have to occur before an adequate number of organs for transplant will be available, in my opinion. One, the adoption of uniform policy and procedures by all acute care hospitals specifically delineating organ donor criteria and appropriate procedures to ensure that the families of all eligible organ donors are afforded the opportunity to donate. It is imperative that all physicians and nurses staffing the emergency rooms and intensive care units in these institutions be thoroughly versed in such policies and procedures.

Second, adequate funding must be provided for an ongoing, consistent and professionally done public education program. This program's goal should be to help the public understand that brain death is death and, further, to persuade and motivate a majority of Americans to become organ donors.

Thank you for the opportunity to appear here today.

Mr. GORE. Thank you, Mr. Hall.

[The prepared statement of Mr. Gary Hall follows:]

ORGAN PROCUREMENT PROGRAM AT THE UNIVERSITY OF TENNESSEE CONGRESSIONAL TESTIMONY

I have been requested to related the activities of our Organ Procurement Program in locating suitable organs for transplantation. My specific remarks will outline my activities related to finding a suitable liver for a small pediatric recipient, such as Brandon Hall, and the general approach to Organ Procurement at The University of Tennessee.

Rarely are organ donors "found" by organ procurement coordinators; rather, organ donors are brought to the attention of coordinators as a result of a referral by health professionals not normally involved in organ procurement.

Locating a suitable liver for a small pediatric recipient involves a two pronged effort: (1) a local effort - an on-going systems approach that will be described later; and (2) a nationwide effort. This involves listing the patient, along with acceptable donor parameters, on a national telephone system called, "The North American Transplant Coordinators Organization 24-Alert" phone system. 24-Alert, an acronym for the telephone number of this service, is accessible from any telephone in North America. Mr. Don Denny, Director of Organ Procurement at The University of Pittsburg, administers the system, and will comment during these hearings relative to the mechanics of this system.

In particularly urgent cases, such as the one involving Brandon Hall. Various organ donor programs are directly contacted to make them aware of our need and requested not to reject infants as organ donors in contrast to the usual policy (infant kidneys are rarely needed for transplants). In these situations our program accepts full fiscal responsibility for the organ retrieval procedure where there is considerable doubt as to the transplantability of the donor's kidneys. To date, we have been successful in procuring a suitable organ for every eligible patient awaiting liver transplantation at our center.

Our local organ procurement program, similar to organ procurement programs in other areas, has been marginally successful in retrieving an adequate number of organs for transplant.

The various attachments to his testimony represent our efforts to develop an understanding of the inhibitions physicians and nurses in our community have toward participating in organ procurement. For a very long time now, organ procurement has been struggling to be universially recognized in our medical community as a valid and legitimate endeavor. Often those in authority in the hospitals in our area, upon which we rely for eligible organ donors, either acquiesce or are apathetic to our requests to be permitted to educate and inform nurses and physicians working in hospital areas where organ donors are most likely to be found.

In contradistinction to the lack of uniform affirmative support for organ donation on the part of hospitals within our area, we have the definite impression that a majority of physicians and critical care nurses favor cadaveric organ donation. This impression is confirmed by positive responses to survey questions concerning physicians and nurses' attitudes toward personal organ donation (Attachments One and Four)

Despite these favorable attitudes, it is clear that a majority of donors are not identified and referred to the Transplant Program (Attachment Three). Furthermore,, it is the perception of most critical care nurses that a majority of eligible donors under their care are not identified nor are their families advised of their right to exercise the organ donor option (attachments Two and Four).

In Attachment Four can be found data suggesting that considerable uncertanity exists on the part of critical care nurses as to their hospital's position on organ donation. This fact further suggests possible contributing causes of the nurses' uncertainty about the identification of eligible organ donors (Attachment Four).

Due to the lack of a uniform systems approach, organ procurement coordinators spend most of their time selling, through, in-service seminars and unscheduled visits to critical care units to acquaint critical care nurses with organ donation procedures. These sessions, generally include an emotional appeal to the nurses to approach families of eligible organ donors or, at the very least, to contact the organ procurement coordinator and permit them to discuss the donation with the potential donor's family.

The foregoing is not intended as an indictment of hospitals, physicians or nurses, nor is it intended to characterize them as apathetic toward the needs of patients awaiting transplantation. These institutions and professionals have some real and legitimate concerns about their participation in facilitating organ donation. These concerns, may be summarized as follows:

I. The majority of organ donations occur in acute care hospitals not associated with organ transplant programs. Consequently, the focus of attention of these hospitals and staff is on aspects of patient care not related to transplantation. Organ donation does not directly benefit their patient population.

II. There exists a general belief on the part of physicians and nurses that organ donation does not enjoy widespread public support. That this notion has merit was confirmed in a public opinion survey conducted by the Gallup Organization earlier this year. This survey, performed for The National Kidney Foundation, found that only 40% of those polled (44% of white participants and 20% of black participants) indicated they were either very or somewhat likely to want their own kidneys donated after their death. Our experience in Memphis, where the proportion of blacks in the population approaches 50%, confirms the findings of the Gallup Survey - approximately 20% of black families approached about organ donation ultimately consent. This circumstance serves to discourage physicians and nurses treating a black patient who dies, and is suitable for organ donation, from approaching the patient's family.

III. A continued major concern is the issue of public acceptance of brain death as the death of the person. Most physicians and a majority of legislators accept the idea that an individual who has suffered irreversible cessation of total brain function, regardless of the continuance of function of other organ systems is legally dead. The level of certainty among critical care nurses is somewhat less that that of physicians (Attachments One and Four). It is not surprising therefore, that a substantial proportion of families have difficulty accepting the explanation that one is dead when they feel a pulse and see them breathing, albeit that these processes are mechanically maintained. It requires a concerned, compassionate and committed physician and/or nurse to spend sufficient time with the family to help them understand that their relative is truly dead. Family acceptance of brain death as death of the individual is absolutely essential before a discussion of organ donation can ensue and be expected to result in consent for organ donation.

In conclusion, two things will have to occur before an adequate number of organs for transplant will be available:

I. The adoption of uniform Policies and Procedures by all acute care hospitals specifically delineating organ donor criteria and appropriate procedures to ensure that the families of all eligible organ donors are afforded the opportunity to donate. It is imperative that all physicians and nurses staffing the emergency rooms and intensive care units in these institutions be thoroughly versed in such Policies and Procedures.

II. Adequate funding must be provided for an on-going, consistent, professionaly done Public Education Program. This program's goals should be to help the public understand that brain death is death and, further, to persuade and motivate a majority of Americans to become organ donors.

Thank you for the opportunity of providing this testimony to your committee.

Gary Hall
Transplant Coordinator

ATTACHMENT NUMBER ONE
PHYSICIAN SURVEY

During the late autumn and early winter of 1979, the attached questionnaire pertaining to physician attitudes towards organ donation was mailed to approximately 1,500 physicians in Memphis and Shelby County, Tennessee. The mailing list comprised those physicians who were active members of the Shelby County Medical Society and resided in Shelby County. This questionnaire was patterned after one utilized by the Nashville Transplant Program in 1972 (see attached reprint.) A total of 574 physicians responded to the questionnaire, approximately 38%.

DEMOGRAPHICS OF RESPONDENTS

Age

Age	Number	Percent
29 or less	135	23.5
30-34	115	20.0
35-39	68	11.8
40-44	60	10.5
45-49	40	7.0
50-54	47	8.2
54-59	48	8.4
60-64	30	5.2
65 or over	29	5.1

Sex

Sex	Number	Percent
Male	507	88.3
Female	51	8.9
Not Answered	16	2.8

Race

Race	Number	Percent
Caucasian	481	83.8
Negro	9	1.6
Oriental	11	1.9
Not Answered	73	12.7

Religion

Religion	Number	Percent
Protestant	387	67.4
Catholic	71	12.4
Jewish	59	10.3
Other Christian	13	2.3
Other Asian Sects	11	1.9
None	22	3.8
Not answered	11	1.9

Speciality

Speciality	Number	Percent
Surgical	126	22.0
Non-Surgical	432	75.3
Not answered	16	2.8

Present Position

Position	Number	Percent
House Staff	159	22.7
Faculty	101	17.6
Private Practice	262	45.6
Other	50	8.7
Not answered	2	0.3

The following tables indicate the responses tabulated to each of the six questions:

8. CADAVERIC RENAL TRANSPLANTATION IS:

A.	Effective	168 (29.3%)
B.	Effective in selected cases	372 (64.8%)
C.	Still experimental	16 (2.8%)
D.	Dangerous or useless	3 (0.5%)
	Not answered	15 (2.6%)

There were no differences in responses by Demographics except for medical specialties in which 45.1% of those identifying themselves as surgeons marked the "A." response as opposed to only 24.8% of the non-surgeons and 31.2% of those not indicating their speciality.

9. ATTITUDE TOWARD KIDNEY DONATION AFTER MY DEATH:

A.	Organ donor card signed	246 (42.9%)
B.	Willing, but card unsigned	211 (36.5%)
C.	Would not sign, but donation acceptable if family consents	80 (14.1%)
D.	Opposed to kidney donation after my death	27 (4.8%)
	Not answered	10 (1.8%)

Considering the "A." and "B." answers as positive responses and the "C." and "D." as negative responses, there were no differences in positive vs. negative responses by age, sex, race, religion, speciality or position. However, when isolating the "A." Responses according to the above demographics several significant differences emerge. In the 40-44 age group, 58.3% claimed to have signed their organ donor card. There were no significant differences by sex. Although the numbers for non-caucasians were small, only 15% of this group vs. 42.9% of the caucasians vs. 50.7% of those not indicating their race claimed to have signed a donor card. The only other significant difference found related to the religion of the respondent: 52.9% of Catholics vs. 30.5% of the Jewish physicians marked response 'A."

10. ATTITUDE TOWARD FAMILY KIDNEY DONATION AFTER THEIR DEATH:

A.	All of age have signed the organ donor card	109 (19.0%)
B.	Not signed, but I would encourage them to do so	251 (43.9%)
C.	I am neutral on the mater of their signing a card	192 (33.2%)
D.	Opposed to kidney donation after their death	11 (1.9%)
	Not answered	11 (1.9%)

Regarding "A." and "B." as positive responses and "C." and "D." as negative responses, there were found to be no significant differences by age, sex or medical speciality of the respondent. Again, the responses among non-Caucasians were few (20), but only 35% of non-Caucasians vs 64.9% of Caucasians responded positively to question 10. Among religious denominations, 50.9% of Jewish physicians and 54.5% of "Other" groups and "None" combined vs 68.6% of Catholic physicians and 65.6% of Protestant physicians responded positively. Seventy-one and four tenths percent of house staff vs. 57.0% of faculty and 59.7% of private practice physicians responded positively.

11. ATTITUDE TOWARD PATIENTS UNDER MY CARE:

A.	Would encourage them to sign organ donor card	286 (49.7%)
B.	If moribund, would encourage family to consent to donation	165 (28.7%)
C.	If moribund, would advise family of right to donate, but not encourage	82 (14.5%)
D.	Would not discuss matter with family at all	25 (4.2%)
	Not answered	16 (2.8%)

There were no significant differences identified when analyzing the data by the various demographic stratifications.

12. CONCERNING THE DIAGNOSIS OF BRAIN DEATH:

A.	Am familiar with and accept criteria of brain death	448 (78.1%)
B.	Not familiar with criteria, but would accept specialist's diagnosis	107 (18.5%)
C.	Death not related to brain function, but rather to cessation of circulation and respiration	7 (1.2%)
D.	No opinion	8 (1.4%)
	Not answered	4 (0.7%)

No differences in responses were identified among the various demographic stratifications.

13. CONCERNING THE MEDICO-LEGAL ASPECTS OF ORGAN DONATION:

A.	State laws provide Medico-Legal protection for organ donation	158 (27.9%)
B.	Not familiar with laws, but feel potential legal liability is minimal	321 (55.7%)
C.	Medico-Legal liabilities are major obstacle to organ donation	33 (5.6%)
D.	No opinion	59 (10.2%)
	Not answered	3 (0.5%)

Although there were no significant differences in the responses by demographic stratifications, it is interesting to note that physicians comprising the four age groups: 30-34, 35-39; 40-44 and 45-49 as a combined group, 8.5% of their number marked response "C." vs only 3.1% of all other age groups combined.

The above survey results should be interpreted with caution since the level of responses does not represent a majority of physicians within the area surveyed. However, the proportionate level of participation is within expected levels compared to other surveys with similar format and method of distribution.

UNIVERSITY OF TENNESSEE
COLLEGE OF MEDICINE

JAMES W. PATE, M.D.
PROFESSOR & CHAIRMAN

LOUIS G. BRITT, M.D.
PROFESSOR & DEPUTY CHAIRMAN

DEPARTMENT OF SURGERY
951 Court Avenue
Memphis, Tennessee 38163

Dear Doctor:

Your help in taking a few minutes to complete the enclosed questionnaire would be deeply appreciated. For your convenience, this form has been layed out to permit ease in return. Of course, return postage has been prepaid.

This study is being conducted under the auspices of the University of Tennessee Renal Transplant Program for the purpose of developing a better understanding of the prevailing views and opinions of physicians in the Mid-South toward renal transplantation and organ donation.

Please rest assured that individual responses will in no way be identified as to their source, thus insuring strict anonymity.

Thank you in advance for your time and cooperation.

Sincerely yours,

Louis G. Britt, M.D.
Director, Renal Transplantation

RENAL TRANSPLANT QUESTIONNAIRE

General Information

(Circle Appropriate Response in Questions 1 through 5)

1. **YOUR AGE:** < 30; 30-34; 35-39; 40-44; 45-49; 50-54; 55-59; 60-64; 65+
2. **SEX:** M F
3. Race: Caucasian Negro Oriental
4. **RELIGION:** Catholic Jewish Prostestant
   Other *(please specify)* ______
5. **YEARS IN PRACTICE:** < 2; 2-5; 6-10; 11-15; 16-20; 21-25; 25+
6. **MEDICAL OR SURGICAL SPECIALTY** ______
7. **PRESENT POSITION** *(Check One)*
   - a. Private Practice ______
   - b. House Staff ______
   - c. Full Time Medical School Faculty ______
   - d. Other *(please specify)* ______

Organ Donation Information

8. **CADAVERIC RENAL TRANSPLANTATION IS:** *(check one)*
   - a. Effective ______
   - b. Effective in selected cases ______
   - c. Still experimental ______
   - d. Dangerous or useless ______
9. **ATTITUDE TOWARD KIDNEY DONATION AFTER MY DEATH:** *(check one)*
   - a. Organ donor card signed ______
   - b. Willing, but card unsigned ______
   - c. Would not sign, but donation acceptable if family consents ______
   - d. Opposed to kidney donation after my death ______
10. **ATTITUDE TOWARD FAMILY KIDNEY DONATION AFTER THEIR DEATH** *(check one)*
    - a. All of age have signed the organ donor card ______
    - b. Not signed, but I would encourage them to do so ______
    - c. I am neutral on the matter of their signing a card ______
    - d. Opposed to kidney donation after their death ______
11. **ATTITUDE TOWARD PATIENTS UNDER MY CARE:** *(check one)*
    - a. Would encourage them to sign Organ donor card ______
    - b. If moribund, would encourage family to consent to donation ______
    - c. If moribund, would advise family of right to donate, but not encourage ______
    - d. Would not discuss matter with family at all ______
12. **CONCERNING THE DIAGNOSIS OF BRAIN DEATH** *(check one)*
    - a. Am familiar with and accept criteria of brain death ______
    - b. Not familiar with criteria, but would accept specialist's diagnosis ______
    - c. Death not related to brain function, but rather to cessation of circulation and respiration ______
    - d. No opinion ______
13. **CONCERNING THE MEDICO-LEGAL ASPECTS OF ORGAN DONATION** *(check one)*
    - a. State laws provide medico-legal protection for organ donation ______
    - b. Not familiar with laws, but feel potential legal liability is minimal ______
    - c. Medico-legal liabilities are major obstacle to organ donation ______
    - d. No opinion ______

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Physicians' Attitudes Toward Organ Donation

HARRY S. ABRAM, MD, ROGER VANDER ZWAAG, PhD, and
H. KEITH JOHNSON, MD,† *Nashville, Tenn*

THE SUPPLY of cadaveric homografts for renal transplantation depends not only upon public attitude toward organ donation but upon the physician who provides care for the dying. Although the former has received some attention,[1-3] the physician's viewpoint has not. This study represents an initial attempt to explore this area.

Method

In October 1972 we circulated by mail a questionnaire to 1,100 physicians in Nashville, Tenn, and surrounding Davidson County (Table 1). In a covering letter we assured strict anonymity and enclosed an addressed, stamped envelope. Aside from general information (age, sex, race, religion, present medical position, medical or surgical specialty, years in practice), we directed four questions (with five graded multiple choice answers for each) toward the physician's attitudes involving the effectiveness of cadaveric renal allografts, the donation of his own kidneys in the event of his death, his family's donation of their kidneys after death, and the manner in which he discussed organ donation with dying patients or their families. Finally we asked for other comments.

Respondents

A total of 542 physicians responded to the questionnaire or 49.3% of the 1,100 questionnaires. A recent study[4] of factors which influence physicians' response to mailed questionnaires indicated response rates varying from 34.23% to 57.07% according to the format (including both design and reproduction process) and postage (primarily first class compared with bulk or third class). Within that study the format and postage most similar to those used in this report had a response rate of 54.47% among a sample size of 380. Hence, a response rate of 49.3% should be considered within the expected range.

Of the respondents, 93.9% were men, 5.5% were women, and three or 0.6% refused to state their sex. Ninety-five and nine tenths percent of the respondents were white. Five respondents refused to state their race. As the response rate was thus very low among the nonwhite physicians in Davidson County, this study provides no reliable information about the influence of race upon physicians' attitudes toward cadaver donation. Clearly the largest percentage (67.2%) of the respondents were Protestant. A majority were interns and residents as is evident from the large number (104) of individuals younger than 29. Half, or 50.7%, of the respondents were engaged in nonsurgical specialties; 32.1% were engaged in specialties requiring some surgical procedures; and 17.2% were engaged in other specialties or failed to answer (Tables 2-4).

Responses

The multiple choice answers to each of the four basic questions described earlier were arranged in decreasing order from a most favorable attitude to a least favorable attitude toward cadaveric renal donation. In those cases where the physician marked more than one answer to a specific question, the answer showing the most favorable attitude was selected.

For analytical purposes, those opinions expressing belief that renal transplants are effective or moderately effective were grouped together; opinions that transplants would soon or had potential to be effective were grouped; and negative opinions and refusals to answer were grouped. Most respondents (85.8%) be-

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Reprint requests to Dr. Abram at the above address.

Presented at The American Society for Artificial Internal Organs, Chicago, April 4, 1974.

TABLE 1

TRANSPLANT QUESTIONNAIRE

General Information

1. Your age————
2. sex————
3. race————
4. religion————
5. Present position (check one):
   a. House staff————
   b. Fulltime medical school faculty————
   c. Private practice————
   d. Other————
6. Medical or surgical specialty————
7. Years in practice————

Cadaver Donation Information

8. I consider renal transplantation using cadaver allografts (check one):
   a. An effective and proven method of treatment————
   b. A moderately effective method of treatment in selected cases————
   c. Still in the experimental stage but will soon become a proven method of treatment————
   d. An experimental procedure with potential for becoming a proven method of treatment but some years off————
   e. A dangerous or useless procedure of no clinical value————
9. Concerning donating my own kidneys in the event of death (check one):
   a. I have signed and carry the Uniform Anatomical Gift Act Card————
   b. I would sign and carry the Uniform Anatomical Gift Act Card if presented to me————
   c. I would hesitate but probably sign such a card————
   d. I would not sign such a card but do not feel upset at the thought that my family might donate my kidneys after my death————
   e. Under no circumstances whatsoever would I want my kidneys used as cadaver organs————
10. Concerning members of my family donating their kidneys after death (check one):
    a. Those of age have all signed the Anatomical Gift Act Card————
    b. I would encourage them to sign such a card————
    c. I would be neutral on the matter of their signing a card, believing such a decision is a personal matter————
    d. I would discourage their signing a card but allow them to do so if they persisted————
    e. I would not allow them to donate their kidneys under any circumstances————
11. Concerning patients who are under my care (check one):
    a. I would actively discuss the Anatomical Gift Act with them while they are in good health and encourage them to donate their kidneys————
    b. If they are moribund I would discuss the matter of donation with the patient's family and encourage them to donate the kidneys after death————
    c. If they are moribund I would discuss the matter with the family and tell them the kidneys could be used without encouraging or discouraging them to make a decision one way or the other————
    d. I would not discuss the matter with the family at all————
    e. I would forbid the family to allow donation even if they insisted to do so————
12. Comments:

lieved that renal transplantation is an effective or moderately effective treatment (Table 5).

The opinions on effectiveness were similar for all religions, for surgical vs nonsurgical specialties, and for all present positions (ie, house staff, faculty, etc). Opinions on effectiveness did differ, however, according to age. Of the physicians younger than 40, 89.2% believed transplants to be an effective or moderately effective treatment. The corresponding percentage for physicians 40 or older was 82.2% The difference in these two percentages is statistically significant ($p < .05$).

Only 7.4% of the respondents had made provision for the donation of their organs (by signing the Uniform Anatomical Gift Act card), although 54.1% or over half the respondents indicated willingness to do so. Responses indicating hesitance, refusal, dislike, or a refusal to answer the question were grouped for analytical purposes, all of these responses being interpreted as a negative attitude toward personal donation of organs. The personal donation status of the respondents was approximately the same for all religions, for surgical vs nonsurgical specialties, and for age (ie,

PHYSICIANS' ATTITUDES TOWARD ORGAN DONATION—Abram et al

TABLE 2

RELIGION OF RESPONDENTS

Religion	*Number*	*Percentage*
Protestant	364	67.2
Catholic	47	8.7
Jewish	40	7.4
Other	10	1.8
"Christian"	16	3.0
Agnostic		
Atheist	65	12.0
None		
Not answered		

TABLE 4

PRESENT POSITION

Position	*Number*	*Percent*
House staff	118	21.8
Faculty	137	25.3
Practice	211	38.9
Other	43	7.9
Not answered	3	0.6

those younger than 40 as compared to those older). The proportion who were already or were willing to be donors did vary significantly ($p = < .02$) according to the present position of the respondent. House staff and faculty had the largest proportions of positive responses (70.9% and 63.5% respectively). Physicians in private practice had the lowest proportion (54.5%) who were already or were willing to be donors. Respondents in positions other than house staff, faculty, or private practice responded positively 58.1% of the time (Table 6).

Sixty-one and six tenths percent of the respondents expressed a neutral attitude about members of their families being potential donors. Only ten respondents said they would discourage or forbid members of their families from being potential donors. Responses concerning family members did not differ significantly with regard to the religion, specialty, present position, or age characteristics of the respondents (Table 7).

Those physicians who gave no answer to the question concerning discussion of the Anatomical Gift Act with patients or their families were excluded from the analysis since their number included many physicians who had little direct contact with patients. The proportion of respondents (excluding those who did not answer the question) who claim to discuss the Gift Act with all their patients is 28.6% This proportion did differ significantly with respect to age ($p < .05$), but not with respect to present position, specialty, or religion. Fewer respondents younger than 40 discussed the Gift Act with their patients than older respondents the percentages being 22.7% and 36.1% respectively (Table 8).

TABLE 3

AGE OF RESPONDENTS

Age	*Number*	*Percent*
29 or younger	104	19.2
30-34	90	16.6
35-39	92	17.0
40-44	65	12.0
45-49	57	10.5
50-54	48	8.9
55-59	35	6.5
60-64	25	4.6
65-69	9	1.7
70-74	8	1.5
75 +	6	1.1
Not answered	3	0.6

Discussion

The above findings point to some preliminary but noteworthy trends. The number of physicians who have actually signed donor cards is surprisingly small (7.4%), even though a majority (54.1%) claim a willingness to sign a card if presented to them. Likewise, few physicians have family members who have signed the Gift Act card (4.1%); another 31.7% state they would encourage their family to do so. This finding suggests that *accessibility of donor cards and increased public information* may improve the proportion of physicians and their families who sign them. Several physicians commented on the lack of information in this area. As one stated, "The Anatomical Gift Act card is a well-kept secret from the public and the medical profession at large." After the completion of this study, the State of Tennessee placed the statement. "Organ Donor, Yes... No...," on its driver's

TABLE 5

OPINIONS ON EFFECTIVENESS

Opinion	*Number*	*Percent*
Effective	204	37.6
Moderately	261	48.2
Effective		
Soon	31	5.7
Potential	34	6.3
Useless	1	0.2
Not answered	11	2.0

TABLE 6

PERSONAL DONOR STATUS

Status	*Number*	*Percent*
Already	40	7.4
Willing	293	54.1
Hesitate	113	20.8
Refuse	79	14.6
Dislike	4	0.7
Not answered	13	2.4

TABLE 8

DISCUSSION WITH PATIENTS

Physicians' Answer	*Number*	*Percent*
Discuss with all	143	26.4
Discuss with moribund	196	36.2
Discuss with family	127	23.4
Not discuss	31	5.7
Forbid		
Not answered	45	8.3

license. Such a move should increase significantly the number of donors within the state.

It is also of note that those physicians in house staff and faculty positions have a higher proportion who are already or are willing to be signers of the Gift Act card. These findings may reflect that more *exposure to transplant programs* stimulated interest and led to knowledge of the need for potential donors. Although younger physicians appear more optimistic than older physicians concerning transplantation as effective treatment, a smaller percentage of them discuss the Anatomical Gift Act with their patients. This finding may relate to the latter's greater life experience and ease with patients, and perhaps to an acceptance of death not present in the younger physician.

TABLE 7

FAMILY DONOR STATUS

Status	*Number*	*Percent*
Already	22	4.1
Encourage	172	31.7
Neutral	331	61.1
Discourage	9	1.7
Forbid	1	0.2
Not answered	7	1.3

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ATTACHMENT NUMBER TWO

CRITICAL CARE UNIT NURSE SUPERVISOR SURVEY

During the first quarter of 1981, the attached survey form was mailed to the nursing supervisors of 6 emergency rooms and 12 intensive care units in 7 hospitals in Memphis. Responses were received from the nursing supervisors of 2 emergency rooms (4 failed to respond) and 11 intensive care units (only one failed to respond) in 7 hospitals.

Although the numbers involved in this survey were small, an insight was gained into the perception of organ donation aspects by nursing supervisors representing greater than 250 critical care nurses.

Question I. results indicated a reasonably good familiarity with hospital policies concerning cadaveric organ donation. There appeared to be less certainty, however, when questioning whether staff were familiar with the policy or whether procedures had been implemented to assure compliance.

The results of Questions II., III. and IV. are self-explanatory. The 10 "never" responses in Question V. would appear to be alarming until it is realized that no patient's personal effects are retained in an intensive care unit.

If the responses in Question VII., "most of the time" and "sometimes" are read as "more than 50% of the time" and "less than 50% of the time", respectively, then in about half the units responding the perception is that organ donation is mentioned more than half of the time while in the remaining half of the responding units organ donation is discussed with families in less than half of the eligible cases.

Question VIII. refers to a bi-monthly newsletter produced and distributed by the Transplant Coordinator to critical care nurses, physicians, social workers, hospital chaplains and hospital administrators. The last issue was distributed in May, 1982. Since that time, there has not been a single inquiry concerning the whereabouts of subsequent issues.

Question IX. refers to a pamphlet designed to give to families of a patient dying or deceased who is medically eligible for organ donation. This pamphlet had been distributed previously to all 18 units surveyed.

Question X. is self-explanatory. Question XI. concerns itself with the matter of inservice educational seminars with critical care nurses in order to familiarize them with the various aspects of their participation in organ procurement. As a matter of practice, it is difficult if not impossible to be permitted to provide inservice seminars in any critical care unit more often than semi-annually. Obviously, if less than 50% of the nurses employed in a unit attend each inservice seminar, it is not possible to acquaint all nurses within any unit about organ donation within any year. Indeed, experience has shown that less than 50% of the nurses in any critical care unit in Memphis have ever attended an inservice program dealing with cadaver kidney donation.

The final question ties in with Question XI. demonstrating that rarely are nurses afforded the opportunity to learn about organ donation.

Hospital____________________ Unit____________________ Name____________________

N.A.=Not Answered

I. Does your institution have a policy regarding cadaver kidney donation?
Yes 10 No 3
A. If yes, have all your staff read the policy statement? Yes 6 No 4 N.A. 3
B. If yes, has your unit implements procedures to assure compliance within the policy statement? Yes 5 No 3 N.A. 5

II. Does your institution have recommended criteria for brain death determination? Yes 8 No 3 N.A. 2
A. If yes, are staff and physicians attending within your unit aware of these criteria? Yes 8 No 0 N.A. 5

III. Is your staff aware of the death circumstances compatible with cadaver kidney donation? All are aware 1 Most 11 Some 1 None 0

IV. Is your staff aware of the medical suitability criteria for cadaver kidney donation? All are aware 1 Most 10 Some 2 None____

V. Does your unit search for a signed organ donor card on dead or dying patients? All of the time 0 Most of the time 1 Sometimes 2 Never 10

VI. Who usually approaches the families of patients dying of a neurological insult concerning kidney donation? Attending Physician 7 Nurse 3 Other____
"Either" 3

VII. How frequently are the families of patients dying of a neurological insult, but otherwise medically suitable kidney donors approached?
All of the time 0 Most of the time 6 Sometimes 5 Rarely 0 Never 1
"Unknown" 1

VIII. Do you receive copies of the monthly U.T. Transplant Program Newsletter?
Yes 11 No 2
A. Does all your staff read these newsletters? Yes 4 No 5 Most 1 Some 2
N.A. 1

IX. Does your unit have a supply of "Gift of Life" pamphlets designed to give to families of potential cadaver kidney donors? Yes 4 No 9
A. If yes, are all your staff aware of their placement in the unit? Yes 3 No 1 N.A. 9
B. Also, if yes, how frequently are the pamphlets used? In every case 0 Most of the time 0 Sometimes 4 Never 0

X. How would you describe the attitudes of your staff towards cadaver kidney donation? Favorable 9 Neutral 4 Opposed 0
A. How would you describe the attitudes of most neurosurgeons attending within your unit? Favorable 9 Neutral 3 Opposed 0 N.A. 1
B. How would you describe the attitudes of other physicians attending patients dying of a neurological insult? Favorable 7 Neutral 4 Opposed 0
N.A. 2

XI. When was the last time an inservice seminar concerning cadaver kidney donation was conducted for members of your staff? < 3 mos. ago 3 3-6mos. ago 1 6mos.-1 yr ago 4 > 1 yr. ago 4 "Probably Never" 1
A. What proportion of your staff attended the last inservice session?
< 10% 1 10%-20% 2 25%-50% 3 50%-75% 3 75%-100% 1 N.A. 3

XII. Do your new nurse orientation procedures provide a segment dealing with cadaver kidney procurement? Yes 4 No 9

Hospital____________________**Unit**____________________**Name**____________________

I. Does your institution have a policy regarding cadaver kidney donation? Yes____ No____

A. If yes, have all your staff read the policy statement? Yes____ No____

B. If yes, has your unit implements procedures to assure compliance within the policy statement? Yes____ No____

II. Does your institution have recommended criteria for brain death determination? Yes____ No____

A. If yes, are staff and physicians attending within your unit aware of these criteria? Yes____ No____

III. Is your staff aware of the death circumstances compatible with cadaver kidney donation? All are aware____Most____Some____None____

IV. Is your staff aware of the medical suitability criteria for cadaver kidney donation? All are aware____Most____Some____None____

V. Does your unit search for a signed organ donor card on dead or dying patients? All of the time____Most of the time____Sometimes____Never____

VI. Who usually approaches the families of patients dying of a neurological insult concerning kidney donation? Attending Physician____Nurse____Other____

VII. How frequently are the families of patients dying of a neurological insult, but otherwise medically suitable kidney donors approached? All of the time____Most of the time____Sometimes____Rarely____Never____

VIII. Do you receive copies of the monthly U.T. Transplant Program Newsletter? Yes____ No____

A. Does all your staff read these newsletters? Yes____No____

IX. Does your unit have a supply of "Gift of Life" pamphlets designed to give to families of potential cadaver kidney donors? Yes____No____

A. If yes, are all your staff aware of their placement in the unit? Yes____No____

B. Also, if yes, how frequently are the pamphlets used? In every case____ Most of the time____Sometimes____Never____

X. How would you describe the attitudes of your staff towards cadaver kidney donation? Favorable____Neutral____Opposed____

A. How would you describe the attitudes of most neurosurgeons attending within your unit? Favorable____Neutral____Opposed____

B. How would you describe the attitudes of other physicians attending patients dying of a neurological insult? Favorable____Neutral____Opposed____

XI. When was the last time an inservice seminar concerning cadaver kidney donation was conducted for members of your staff? < 3 mos. ago____3-6mos. ago____ 6mos.-1 yr ago____ > 1 yr. ago____

A. What proportion of your staff attended the last inservice session? < 10%____10%-20%____25%-50%____50%-75%____75%-100%____

XII. Do your new nurse orientation procedures provide a segment dealing with cadaver kidney procurement? Yes____No____

ATTACHMENT NUMBER THREE

A STUDY TO IDENTIFY POTENTIAL ORGAN DONOR AVAILABILITY

During the period of April through August, 1981, in cooperation with the Organ Procurement Unit of The Center for Disease Control, a study of the charts of patients dying in 12 acute care hospitals during calendar year 1980 within a 15 mile radius of The University of Tennessee-Memphis was conducted in order to assess the potential availability of organ donors.

A chart reviewing instrument (containing this center's specific organ donor medical acceptability criteria) was developed in concert with the C.D.C. Mr. Michael Rich of the C.D.C. and Gary Hall, U.T. Transplant Coordinator visited the various hospital administrators to obtain consent for the conduct of the study. All hospitals agreed to participate.

The study was actually conducted by Gary Hall and was divided into four phases: (1) Death Register Tabulations; (2) Patient Chart Review; (3) Tabulation and Analysis of Chart Review Results; and (4) Report of Review Results and Analysis to Participating Institutions.

I. Death Register Tabulation. In preparation for the actual chart review, the Death Register for Emergency Room and In-hospital Deaths for each of the 12 hospitals was reviewed. Patients dead on arrival were excluded from the tabulations. Of the remainder, those deaths of patients whose ages were less than one or greater than 59 years of age were excluded. Finally, those deaths in which the Death Register noted a cause of death (e.g. cancer, infection, etc.) which is a contraindication to organ donation were excluded.

II. Chart Review Results. Six hospitals were selected for inclusion in this phase of the study. These six institutions accounted for 330 emergency room deaths and 4,463 in-hospital deaths or approximately 80% of the total deaths tabulated from the 12 hospitals' death registers. After the actual chart review was initiated, one of the hospitals was eliminated from this phase when it was found that the patient charts contained inadequate documentation to permit a reliable assessment of any specific patient's medical suitability for organ donations. That hospital's data (representing 110 emergency room deaths and 620 in-hospital deaths) was then combined with the Death Register Data from the six hospitals not selected for actual chart review.

The actual number of patient charts reviewed is indicated in the first column of Section II. on the attached, "Chart Review Results" sheet. All 25 remaining emergency room death charts and 316 charts of patient dying after admission to the hospital were reviewed (fourteen charts selected for review were unavailable at the time of the review and another 57 charts from a single institution were randomly selected out from the review since their inclusion would have resulted in exceeding the preagreed limit of 150 charts for review from a single institution).

Under the category of "Donors" in Section II. of the attached "Chart Review Results" sheet are three columns which relate the chart review findings to actual results in 1980. The "Identified" column denotes those deaths in which the chart review found medically accepted brain-dead individuals (16 donors were included in this column to account for the expected incidence among the 71 patient charts not reviewed). Charts of patients which had insufficient data or in which there was not a clear indication of the existence of brain-death were excluded. The "referred" column indicates the number of referrals of patients who were medically acceptable for organ donation to the transplant program from the five hospitals reviewed. The final column "Recovered" denotes the number of such referred patients who actually became donors.

The results obtained from the above review and tabulations were then applied to the Death Register Tabulations from the other seven hospitals in which an actual patient chart review was not conducted. These results were reflected in Section II.a. of the attached "Chart Review Results" sheet.

Since there is no difference between the two groups of hospitals in terms of the character of emergency room patient characteristics, a factor of 5% (the proportion of E.R. deaths in Section II. found to be suitable for organ donation) was applied to the E.R. deaths tabulated among the seven hospitals in which the review was not conducted. In-hospital patient characteristics within this group of seven institutions (with the exception of two hospitals representing a total of approximately 800 in-hospital deaths) is not the same as in the five institutions actually reviewed. Accordingly, the proportion of in-hospital deaths found to be suitable for organ donation (2.3+%) among the five institutions actually reviewed was arbitrarily cut in half (1.2%) when applied to the seven hospital group's data.

The resultant data included in Section III. (Combined Totals) is felt to be a conservative assessment of the actual potential availability of donors among the twelve acute care hospitals studied for calendar year 1980.

CONCLUSIONS: The incidence of medically acceptable cadaveric organ donors in Memphis, Tennessee, in calendar year 1980 was determined to be 140 (2.3% of 6,154 tabulated hospital deaths). During calendar year 1980, 35 patients (an estimated 25% of those available) who were medically acceptable for organ donation were referred to the Transplant Program. Thirteen patient families (37%) refused organ donation with the result that 22 patients (63%) actually were donors. The documented estimated referral efficiency (25%) does not account for those cases where hospital personnel approached patient families about organ domation, were refused and never therefore , contacted the Transplant Program. However, candid conversations with key critical care nursing personnel support the inescapable conclusion that a majority of suitable donors are never identified by attending hospital and medical staff and their families are not advised of their right to donate.

CHART REVIEW RESULTS - 1980 HOSPITAL DEATHS
MEMPHIS, TENNESSEE

I. DEATH REGISTER TABULATIONS (NON-DOA DEATHS IN 5 HOSPITALS ACTUALLY REVIEWED)

	DEATH	AGE EXCLUDED (<1 or >59)	MEDICAL CONTRAIND.	NET TOTAL
ER	220	178	17	25
In Hosp.	3,843	2,804	652	387
TOTAL	4,063	2,982	669	412

II. CHART REVIEW RESULTS (5 HOSPITALS WHERE WHERE CHARTS ACTUALLY REVIEWED)

	CHARTS REVIEWED	DONORS		
		IDENTIFIED	REFERRED	RECOVERED
ER	25	11 (5%)+	4(44%)	2(22%)
In Hosp.	316	87*(2.3%)+	20(23%)	16(18%)
Total	341	98(2.4%)+	24(24%)	18(18%)

*Includes number (16) expected to be found in charts not reviewed (71).
+Proportion of total death in I. above

I.a. DEATH REGISTER TABULATIONS (NON-DOA DEATHS IN 7 HOSPITALS NOT ACTUALLY REVIEWED)

DEATH	AGE EXCLUDED* (<1 or >59)	MEDICAL* CONTRAIND.	NET TOTAL
444	252	---	192
1,647	1,294	30	323
2,091	1,546	30	515

* Some Death Registers did not note age or cause of death.

I.b. EXPECTED CHART REVIEW RESULTS (7 HOSPITALS WHERE CHARTS NOT ACUTALLY REVIEWED)

NET TOTAL FROM I.a. ABOVE	EXPECTED # DONORS		
	IDENTIFIED	REFERRED+	RECOVERED+
192	22(5%)*	4(22%)	2(11%)
323	20(1.2%)*	7(35%)	2(10%)
515	42(2.0%)*	11(26%)	4(10%)

+ Actual recorded results
* Proportion of total deaths in I.a. above

III. COMBINED TOTALS (II. AND IIa. ABOVE)

	EXPECTED # DONORS		
	IDENTIFIED	REFERRED+	RECOVERED+
ER	33(5%)*	8(24%)#	4(12%)#
In Hosp.	107(1.7%)*	27(25%)#	18(17%)#
Total	140(2.3%)	35(25%)#	22(16%)#

* Proportion of total deaths from combined totals of I. and I.a. above
+ Actual recorded results.
# Proportion of total in "IDENTIFIED" # Column

IV. IDENTIFIED DONORS - ETIOLOGIC/DEMOGRAPHIC PROFILES
(5 HOSPITALS WHERE PATIENT CHARTS ACTUALLY REVIEWED)

	CAUSE OF DEATH		
SEX/RACE*	TRAUMA	NON-TRAUMA	TOTAL
MC	29(10)	13(4)	42(14)
FC	8(4)	24(4)	32(8)
MN	8(1)	4(1)	12(2)
FN	2	10	12(0)
TOTAL	47(15)+	51(9)+	98(24)+

* MC = Male Caucasian; FN = Female Negro, etc.
+ Indicates actual donor referrals
Mean Donor Age = 32.7 years

ATTACHMENT NUMBER FOUR
SURVEY OF CRITICAL CARE NURSES' ATTITUDES TOWARDS ORGAN PROCUREMENT

A survey of critical care nurses' attitudes towards the various aspects of organ donation and organ procurement was conducted during the late autumn of 1982. Four hundred survey forms (a sample of which is attached) were distributed through the unit nursing supervisors in 10 emergency rooms and 18 intensive care units in 11 hospitals with instructions for the form's completion and return of the surveys to Gary Hall, U.T. Transplant Coordinator. One hundred Seventy-five completed surveys from 6 emergency rooms and 7 intensive care units in 7 hospitals were returned. One hospital (representing one E. R. and two intensive care units) refused to participate. Effforts to retreive the surveys from the remaining 3 E. R.'s and 9 intensive care units were abandoned after repeated attempts.

On the attached sheets are tabulated the responses in percentages for each question. The last column tabulates the responses for all participants. In the first four columns, responses are stratified according to the participants' responses to two key questions- Question 4 under "Organ Donation Information" ("Attitude toward organ donation after my death") and Question 3 under "Brain Death Information" hereinafter referred to as Question 3, Section II. The first four questions are keyed as follows: Column I-those respondents who marked "a" or "b" in Question 4, Section I and "yes" to Question 3, Section II; Column II - those respondents who marked "a" or "b" in Question 4, Section I and "no" on Question 3, Section II; Column III - those respondents who marked "c" or "d" on Column 4, Section I and "yes" on Question 3, Section II; and Column IV - those respondents who marked "c' or "d" on Question 4, Section I and "no" on Question 3, Section II. The columnar percentages in each question will not necessarily total 100% since the percentages listed indicate the proportion of survey forms on which that choice was selected, thereby accounting for more than one choice selected per question.

Analysis of the responses according to demographics has not been noted here due to the following: (1) Age - no significant differences were found by age grouping; (2) Sex - all but seven of those indicating their sex were females; (3) Race - all but 12 of those indicating their race were white; (4) Religion- all but 27 of those indicating their religion were Protestant, and (5) Position - 141 of the 175 respondents were registered nurses.

A detailed analysis of the results will not be related here, but several findings of importance and relevance will be noted. These findings suggest that nurses' personal attitude toward organ donation and/or brain death do impact on their willingness to participate in organ procurement. This conclusion is confirmed by reviewing the results of the following questions:

(1) Question 2, Section I - under Column IV, 56% of the respondents indicated they felt organ donation to be either valid only if the patient has a signed organ donor card or "a fruitless and nonproductive act."

(2) Question 3, Section I - about 90% of the respondents under columns I and II (those with a favorable attitude toward personal organ donation) indicated a willingness to take affirmative, independent action to encourage organ donation with their patients or their families compared to only about 45% of the respondents under columns III and IV (those with unfavorable attitudes toward personal organ donation) who would take such action.

(3) Question 7, Section I - this question concerns the nurse's perception of the frequency with which the families of patients under their care who are medically suitable for organ donation are approached. The most distressing finding is that 76% of all respondents indicated that families of potentially eligible organ donars are approached "sometimes", "rarely", or "never"! Another way of expressing this point is that three quarters of the nurses perceive that less than half the eligible patients under their care ever have an opportunity to become donors.

In addition to nurses' inhibitions to unequivocal participation in organ procurement emanating from personal attitudes toward organ donation and brain death, Question 9, section I indicates considerable uncertainty as to the hospitals' postion with respect to organ donation. Although this fact does not solely account for considerable uncertainty regarding eligible donor identification (as determined from the responses to question 10 and 11), it would seem to follow that if one is not sure of his employer's position or support for a program, he is less likely to acquaint himself with that program's needs and requirements.

Finally, the results of this survey do serve to reassure this transplant program that their exists in Memphis widespread medical community support for and participation in facititating organ donation. However, the survey confirms our conviction developed from the previous hospital patient death chart review that a majority of eligible donors are never identified and the families not offered the organ donation option.

TABLUATED RESULTS
CRITICAL CARE NURSES' SURVEY

ORGAN DONATION INFORMATION

		I.(80)	II.(30)	III.(22)	IV.(27)	TOTAL(175)
1.	a.	41%	40%	23%	15%	33%
	b.	60%	47%	77%	63%	58%
	c.	1%	10%	5%	7%	4%
	d.	0	3%	0	11%	3%
	n.a.	1%	0	5%	4%	3%
2.	a.	69%	67%	50%	30%	58%
	b.	20%	17%	32%	11%	21%
	c.	10%	20%	14%	52%	19%
	d.	0	0	0	4%	1%
	n.a.	1%	0	5%	4%	3%
3.	a.	39%	40%	14%	7%	26%
	b.	48%	57%	32%	37%	41%
	c.	34%	40%	68%	52%	34%
	d.	1%	3%	5%	7%	3%
	n.a.	1%	0	0	4%	5%
4.	a.	70%	47%	-	-	42%
	b.	30%	53%	-	-	24%
	c.	-	-	64%	74%	22%
	d.	-	-	36%	26%	10%
	n.a.	-	-	-	-	3%
5.	a.	64%	50%	32%	41%	51%
	b.	28%	23%	9%	7%	19%
	c.	10%	27%	50%	41%	25%
	d.	0	0	9%	11%	3%
	n.a.	0	0	0	0	1%
6.	a.	38%	37%	18%	19%	30%
	b.	52%	47%	59%	41%	52%
	c.	6%	3%	9%	11%	7%
	d.	1%	17%	9%	22%	8%
	e.	30%	30%	45%	26%	34%
	f.	25%	20%	23%	11%	19%
	g.	4%	0	5%	4%	5%
	h.	4%	0	5%	4%	3%
	n.a.	1%	7%	0	0	3%
7.	a.	1%	0	0	0	2%
	b.	20%	3%	5%	4%	19%
	c.	42%	47%	27%	15%	46%
	d.	16%	40%	41%	44%	27%
	e.	4%	7%	23%	41%	3%
	n.a.	2%	3%	5%	0	4%

TABULATED RESULTS

CRITICAL CARE NURSES' SURVEY

ORGAN DONATION INFORMATION

		I.(80)	II.(30)	III.(22)	IV.(27)	TOTAL(175)
8.	a.	8%	13%	9%	19%	14%
	b.	4%	10%	32%	19%	12%
	c.	2%	0	-	4%	2%
	d.	5%	0	5%	4%	5%
	e.	72%	70%	18%	30%	53%
	f.	8%	3%	27%	22%	11%
	n.a.	2%	3%	9%	11%	7%
9.	a.	55%	47%	41%	26%	47%
	b.	1%	3%	9%	7%	3%
	c.	44%	50%	45%	63%	46%
	n.a.	0	0	5%	4%	3%
10.	a.	71%	40%	64%	33%	57%
	b.	29%	60%	32%	67%	41%
	n.a.	0	0	5%	0	3%
11.	a.	68%	33%	55%	48%	54%
	b.	30%	63%	41%	52%	41%
	n.a.	2%	3%	5%	-	5%
BRAIN DEATH INFORMATION						
1.	a.	9%	3%	0	7%	6%
	b.	66%	67%	73%	48%	63%
	c.	24%	13%	23%	33%	22%
	d.	0	3%	5%	15%	3%
	n.a.	1%	13%	0	4%	7%
2.	a.	69%	90%	73%	67%	69%
	b.	19%	3%	27%	22%	17%
	c.	0	0	0	0	0
	d.	11%	7%	0	4%	9%
	n.a.	1%	0	0	7%	5%
3.	a.	100%	0	100%	0	59%
	b.	0	100%	0	100%	34%
	n.a.	0	0	0	0	7%

n. a. = not answered

numbers in parenthesis next to the column headings denote number of respondents in each category.

Dear Colleague:

The maintenance of a viable organ retrieval program is essential in the effort to meet the needs of the many victims of end-stage organ failure who are currently waiting for the chance to be transplanted in the greater Memphis region. Fundamental to the success of this program is the willingness of acute care personnel to participate in the referral of potentially suitable organ donor candidates. As a member of an acute care team, your opinions and perceptions of the various elements involved in solid organ donation are vitally important.

Attached is a confidential questionnaire designed to gather your impressions. Please take a few brief moments to candidly give us your opinions and return the completed form to your unit supervisor. Your responses will be used to help us become more aware of your satisfaction with the program and thereby help us to improve our performance. Please feel free to add any additional comments or suggestions.

Thank you very much for your time and cooperation.

Sincerely yours,

Gary Hall, Transplant Coordinator
Renal/Hepatic Transplant Program

SOLID ORGAN DONATION QUESTIONNAIRE

GENERAL INFORMATION

1. Your Age:________ 2. Sex:_________
3. Race:_____ 4. Religion (optional)______
5. Position (RN, LPN, etc.)_____________
6. Years in practice___________________
7. Hospital:__________________________
8. Unit(e.g. 10th floor, ICU):____________

ORGAN DONATION INFORMATION
(Please check only one response)

1. Cadaveric solid organ transplantation is:

_____a. Effective and proven.
_____b. Effective in selected cases.
_____c. Experimental, but soon to be proven.
_____d. Dangerous, no clinical value.

2. I consider organ donation to be:

_____a. A valid and humanitarian act in all eligible cases.
_____b. A valid and humanitarian act for the family even if patient's wishes unknown.
_____c. A valid and humanitarian act only if patient has signed donor card.
_____d. A fruitless and nonproductive act.

3. Concerning patients under my care: (Check any)

_____a. Would encourage them to sign organ card.
_____b. If moribund, would encourage family to consent to donation.
_____c. Would refer such patients and families to retrieval program for their guidance.
_____d. Would never discuss matter with patients or families nor refer them to organ retrieval program.

4. Attitude toward organ donation after my death:

_____a. Organ Donor Card signed.
_____b. Have not signed card, but willing to.
_____c. Would not sign card, but idea of donation acceptable if my family agreed
_____d. Opposed to organ donation after my death.

5. Concerning organ donation of a member of my family:

_____a. I have discussed organ donation with them and am willing to follow their wishes.
_____b. I would be willing to donate their organs even though I have not discussed it with them.
_____c. I have never thought about consenting to organ donation for a family member.
_____d. I would never donate their organs, regardless of their intentions.

6. The request of organ donation should be made: (Check any)

_____a. In every eligible case.
_____b. Only after the family accepts that the patient will not survive.
_____c. Only if family is not too upset.
_____d. Only if family requests it.
_____e. By patient's physician.
_____f. By patient's nurse
_____g. Only by a member of retrieval team.
_____h. Other_____________________________

7. How frequently are the families of patients under your care who are medically eligible for donation approached?

_____a. Always; _____b. Most times;
_____c. Some times; _____d. Rarely;
_____e. Never.

8. My Personal reservations about organ donation are:

_____a. I may not really be dead when my organs are removed.
_____b. I can't accept the idea of my body being "cut on" after I die.
_____c. I am dubious about the worth of organ donation.
_____d. The doctors will not be aggressive in treating while I'm alive if I'm an organ donor.
_____e. No reservations.
_____f. Other_____________________

9. Does your hospital have a policy regarding solid cadaveric organ donation?

_____a. Yes; _____b. No; _____c. Don't know

10. Are you aware of the death circumstances compatible with cadaveric solid organ donation?

_____a. Yes; _____b. No.

11. Are you aware of the medical suitability criteria for cadaveric solid organ donations?

_____a. Yes; _____b. No.

BRAIN DEATH INFORMATION (Check one)

1. The criteria physicians use in my hospital to declare brain death are:

_____a. Absent respirations, fixed-dilated pupils, no response to painful stimuli.
_____b. All of a. above and flat EEG's or angiography.
_____c. Depending on circumstances, either a. or b.
_____d., No standard criteria.

2. The patient declared brain dead should:

_____a. Be removed from artificial support only after the family consents to it.
_____b. Be removed from artificial support without involving the family in the decision.
_____c. Be treated aggressively regardless of the family's wishes.
_____d. Other_____________________

3. In my opinion, it is acceptable to remove a brain-dead donor's organs after the patient is declared brain dead and before the heart stops beating:

_____a, Yes; _____b. No.

Comments and Suggestions:_____________________

Mr. **Gore**. I am going to hold my questions to the panel to a minimum, and I would ask my colleagues to do so as well, because of the doctor's travel plans.

First of all, just briefly, we are going to go into the specific suggestions that you, Dr. Williams and you, Mr. Hall have provided to us in detail later in this hearing today and tomorrow. But I want to elicit from you two points.

First of all, Dr. Williams, your experience is that of a doctor who spent, I believe, 6 weeks under Dr. Starzl and then came back and, on your own, upgraded the skills that you learned in a relatively brief time with Dr. Starzl and then implemented this new program at the Medical Center in Memphis. That experience suggests that we are likely to see a dramatic increase in the number of centers and in the number of transplant operations in the next few years all across the country. Is that correct?

Dr. **James Williams**. Yes.

Mr. **Gore**. As a result, the demand for transplantable organs is likely to increase dramatically as well; is that correct?

Dr. **James Williams**. Yes.

Mr. **Gore**. And the experiences that Mrs. Hall has had and that Captain Broderick has had are going to become quite commonplace in the United States unless we figure out a way to respond to it on a national basis; is that correct?

Dr. **James Williams**. Yes.

Mr. **Gore**. All right.

One of the hurdles that your patients face is money. You have got the problem of paying for the operation, you have the problem of procuring the transplantable organ, and you have the problem of insufficient awareness on the part of the American people as to how important it is for people to be willing to donate organs after they die; correct? Those are the three hurdles?

Dr. **James Williams**. Yes.

Mr. **Gore**. In your case, Captain Broderick, you face that first hurdle. Your child can't qualify as a candidate in this particular program because you don't cross that first threshold. You don't have a way to pay for the operation. You are an active-duty captain in the U.S. Army, and the U.S. Government refuses to pay the amount of money necessary to save your child's life. Is that correct?

Captain **Broderick**. Yes, sir.

Mr. **Gore**. I find that really hard to believe. Without objection, I would like to put into the record of this hearing a letter from the Assistant Secretary of Defense, Dr. John F. Beary III, to you, Dr. Williams, where he says a second consideration in denying approval of this procedure is the fact that other federally funded health programs, as well as other third-party payers, consider the procedure to be investigational. An additional concern is the high cost of the procedures, typically $50,000 to $60,000, versus the expected long-range benefit to be derived.

[The information follows:]

ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

HEALTH AFFAIRS

04 MAR 1983

James W. Williams, MD.
Associate Professor
The University of Tennessee,
Center for the Health Sciences
Memphis, Tennessee 38163

Dear Dr. Williams:

Lieutenant General Mittemeyer, in response to your December 3, 1982 letter, has asked me to review our policy regarding coverage of liver transplants by CHAMPUS. Although there is no question that there are patients who have derived benefit from liver transplants, there are several factors I have considered which lead me to conclude that the procedure is still properly classified as investigational.

First, there are very few facilities in the United States which have liver transplant programs. Although the University of Pittsburgh, for example, has had great success with liver transplants, a number of other facilities have had high mortality rates in performing the procedure. Thus, since the procedure cannot be readily replicated nor be provided with a predictable level of success at a significant number of facilities, it does not meet the "generally accepted standards of usual professional medical practice in the general medical community" criteria required to be a covered service under the CHAMPUS program.

A second consideration is the fact that other federally funded health programs as well as other third-party payors also consider the procedure to be investigational. An additional concern is the high cost of the procedure, typically $50,000-60,000, versus the expected long-range benefit to be derived.

It is unfortunate that denying liver transplants as a covered service under CHAMPUS will result in hardships on some of our service members. However, in keeping with my responsibilities as Acting Assistant Secretary of Defense for Health Affairs, I cannot recommend that CHAMPUS benefits be expanded to cover liver transplants until the procedure becomes more widely accepted and practiced by the medical community. We must attempt to assure that high quality care is provided to our beneficiaries in all situations.

I appreciate your concern in this matter.

John Beary

John F. Beary, III, M.D.
Acting Assistant Secretary

cc: Lieutenant General Mittemeyer

Mr. **Gore**. I share your reaction to that as repugnant, Captain Broderick, and I will recommend at the conclusion of this hearing today—not waiting for the committee report—that this subcommittee immediately, as a subcommittee, call upon the U.S. Government and the Defense Department who runs this CHAMPUS program to immediately change its policy and allow for the payment for this procedure. It is not investigational or experiemental. It is necessary to save your child's life. I will ask my colleagues to join in that recommendation later today.

Mr. Hall, it is true, is it not, that with so many patients, with so many people needing organs to be donated, that the availability of funds is a factor that institutions take into account—they must, of necessity, take that into account; is that correct?

Mr. **Gary Hall**. That is correct.

Mr. **Gore**. As Mrs. Hall leaves and gets on the plane to fly back to Memphis, Captain Broderick is still faced with the problem of trying to pay for this operation. This really shouldn't be a consideration for professionals such as you and Dr. Williams; is that correct?

Mr. **Gary Hall**. No, it shouldn't.

Mr. **Gore**. All right. I am sorry to rush through my questions, but because of the time constraint, I wanted to do that.

Congresswoman Schneider.

Mrs. **Schneider**. Thank you.

I would like to know from any member of the panel if you are aware of whether or not the American Medical Association or the American Hospital Association is intimately involved in developing uniform policy?

Mr. **Gary Hall**. We have no knowledge of that at this time.

Mrs. **Schneider**. And the AMA is not involved in a uniform policy?

Dr. **James Williams**. Not that I am aware of directly.

Mrs. **Schneider**. It certainly seems to me that that is one good place to start. I don't know that this body would be in a position or even inclined to make mandatory requirements on the hospitals, but it seems that you folks have certainly delineated how we could get around this problem.

I am anxious to know how we in Congress might be able to assist you, Mr. Hall, in improving the rate of donation of organs for transplant surgery? Is there something we could do in this body?

Mr. **Gary Hall**. I thought about that. I don't know that any sort of mandatory regulations are in order. I think that this body can be influential in encouraging the various parties that have to cooperate in an organ procurement procedure to get together at a national level and at the various regional and local levels to try to come to grips with solving the problems of oversight and omissions that occur every day in this country, in that donors are not identified, and a family is not offered the option to donate.

Dr. **James Williams**. If I might add just one comment to what Mr. Hall said, it is a problem of education, educating the public. There is not a person in this group here who, when they die, there will be any question about what happens to their organs. We know what can happen. The general public doesn't know. The technology has rapidly advanced. People who are now of child-bearing age and of donor age were educated at a time when liver transplantation or heart transplantation did not occur. So, the technology, I think—the feasibility of doing these things has not been disseminated, it is not understood. So it is clearly a matter of public education.

Mrs. **Schneider**. Obviously, the public media has an enormous role to play, more so than the Members of Congress.

I am anxious also to know about your interpretation. How long have we been transplanting livers, how many years?

Dr. **James Williams**. I would like to leave those questions to Dr. Starzl, the person who is going to testify later. He is the father of this effort. He has taken it from the very beginning and literally pushed it into the position that it is today.

Mrs. **Schneider**. Very fine.

Most of my other questions, Mr. Chairman, have to do with the medical aspects, so I will hold my questions for the next panel.

Mr. **Gore**. Fine.

Congressman Scheuer.

Mr. **Scheuer**. I will defer questions until the next panel, Mr. Chairman.

Mr. **Gore**. Fine.

Mr. **Scheuer**. I do want to say that I deeply share your sense of outrage and sense of deep concern about the posture of the Federal Government in denying this life-enhancing and life-saving therapy to patients who would otherwise die.

Mr. **Gore**. Congressman Durbin.

Mr. **Durbin**. I would just like to ask the panel in general if there has been any effort or discussion about putting together regional centers for coordination of hospital activities so that there will be, at least on a regional basis, some sort of outreach to small communities and the medium-size hospitals that may not be aware of the need?

Mr. **Gary Hall**. The organ procurement evolved as a result of the need for kidney transplantation, and organ procurement that is directed as close to home as possible has generally been found to be the most effective. I don't know that there are any efforts afoot to develop any regional programs, other than regional organ sharing programs which will be addressed later.

Mr. **Durbin**. Thank you very much.

I will hold any further questions for the next panel.

Mr. **Gore**. Congressman Dan Glickman.

Mr. **Glickman**. Thank you, Mr. Chairman.

I would like to ask you if you think the Government should engage in some sort of national data bank for disclosure of organs for transplant? I understand there are regional networks, which you touched on briefly, but perhaps Mr. Hall or somebody else may want to talk about it. Should the Federal Government establish a national coordinating information data bank for available organs for transplant?

Mr. **Gary Hall**. I can't make a judgment on that.

Mr. **Glickman**. Is the existing system adequate? I understand the southeastern area of the United States, and Florida in particular, has a pretty good system.

Dr. **James Williams**. I think the problem is not in matching the donor with the potential recipient. The problem is identifying and getting the donor. Once the family has given permission for the removal of those organs, from then on, the existing data banks, computer banks, are able to match the suited recipient.

Mr. GLICKMAN. Is there anything the Federal Government can do to encourage donor participation?

Dr. JAMES WILLIAMS. Those are the things that I am not by training equipped to say. I can identify the things I would like to have done, but who does it, I——

Mr. GORE. Would my colleague yield?

Mr. GLICKMAN. Yes.

Mr. GORE. The third panel today is going to provide us with a number of suggestions, some of which the subcommittee will be including in its recommendations, I anticipate.

Following up on your question to Mr. Hall about a nationwide system, how many separate organ procurement systems did you contact in Brandon Hall's case, Mr. Hall?

Mr. GARY HALL. It was in excess of 30.

Mr. GORE. So you have to go to 30 separate organ procurement networks in your search for an organ for this child.

How many organs are available for transplant but are unusable because they don't get matched with a recipient in time? Isn't it about 25 percent?

Mr. GARY HALL. That is true with kidneys. It is not quite that high. But that is true with kidneys. I have no information relative to other organs.

Mr. GORE. No figures on livers?

Mr. GARY HALL. Those that are actually excise and not used.

Mr. GORE. Presumably that percentage could be reduced if we had one network instead of you having to search through 30 separate networks; is that a reasonable assumption?

Mr. GARY HALL. The figure of 20 percent is really not an accurate figure. Most of those organs that are discarded are not discarded for lack of finding an available recipient, they are discarded for other reasons. Only about a 5-percent figure is a more accurate figure for organs discarded for lack of an available recipient at a specific time.

Mr. GORE. I see.

Before closing, Mrs. Hall, I understand that three of Brandon's nurses from LeBonheur Hospital paid their own way to come to the hearing today with you and Brandon. Have you been receiving pretty good medical treatment back in Memphis?

Mrs. BILLIE HALL. We always received good medical treatment at LeBonheur. You wouldn't believe how good they are to us.

Mr. GORE. Captain Broderick, I understand that Adriane's case has attracted the interest and attention of the White House, and you have received some special attention there; is that correct?

Captain BRODERICK. I personally have not had any contacts with the White House, sir.

Mr. GORE. I didn't ask that question to elicit that answer. It was based on a mistaken assumption. I do know that they have an ombudsman over there who works practically full time just on this matter.

Dr. Williams?

Dr. James Williams. Yes; we have been in contact with Mr. Battan, and it appears as though the President is very interested in this problem and is applying pressure to CHAMPUS as well.

Mr. Gore. We are going to apply some pressure today. I hope and expect a unanimous subcommittee action.

Let me thank all of you for helping in this effort to improve the system for acquiring organs for transplantation.

We wish you good luck and God speed, Mrs. Hall and Brandon.

Mrs. Billie Hall. Thank you.

Mr. Gore. Captain Broderick, we will be doing everything we possibly can to assist you in your continuing efforts on behalf of your daughter, and also on behalf of other families around the country that are in this same predicament.

Captain Broderick. Thank you very much, sir.

Mr. Gore. Thank you all.

Our next witnesses include some of the most distinguished doctors in the entire world. With your indulgence, and you have already shown us a great deal, I must tell you that we have a vote on the floor of the House. We will recess for approximately 6 minutes, and then we will come back.

[Recess.]

Mr. Gore. The subcommittee will come back to order.

We are truly honored to have on this panel distinguished physicians. Dr. Shumway and Dr. Starzl are truly the pioneers in their respective fields, the leading transplant surgeons in their world. Dr. Shumway almost single-handedly rescued the heart transplant procedure from a disappointing start in another decade and made it the life-saving procedure that it is today.

Dr. Tom Starzl single-handedly pioneered the liver transplant procedure which, as we have heard, is becoming, if not commonplace, then certainly a regular part of medicine's ability to save lives.

Dr. G. Melville Williams, in addition to being a distinguished surgeon, is the president of the American Association of Transplant Surgeons.

To all three witnesses, let me extend on behalf of the subcommittee our thanks for your willingness to come and join us in this effort. We know it is most unusual for you, Dr. Shumway and you, Dr. Starzl, to speak publicly. You are often too busy in the operating room and, for other reasons, you just don't speak out publicly. We appreciate very much your willingness to come here—particularly, Dr. Starzl, in light of the fact you were up all night. We don't appreciate you any less, Dr. Shumway. But the fact that you were willing to come here after having been up all night on a liver transplant operation really testifies to your recognition of how great the need is for this country to move forward.

Without further ado, Dr. Shumway, we will begin with you.

STATEMENTS OF NORMAN SHUMWAY, M.D., PROFESSOR OF SURGERY, STANFORD UNIVERSITY SCHOOL OF MEDICINE, STANFORD, CALIF.; THOMAS E. STARZL, M.D., PROFESSOR OF SURGERY, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE, PITTSBURGH, PA.; AND G. MELVILLE WILLIAMS, M.D., PROFESSOR OF SURGERY, JOHNS HOPKINS HOSPITAL, BALTIMORE, MD.

Dr. SHUMWAY. Thank you.

I speak for the entire panel that we are grateful for this opportunity to say a few things about the transplantation of tissues in each of our particular specialties.

First, let me make a few general comments regarding the present status of heart and heart-lung transplantation. I would like then to focus on the somewhat special problems associated with heart and heart-lung donors.

During the last decade, tremendous progress has been made in the science and practice of transplantation. New drugs have become available to control more effectively the immune response to transplanted tissues. As a matter of fact, since we began the use of cyclosporine A in December 1980, there has not been a single instance of clinically diagnosable rejection of the allografted heart. In other words, no patient has shown any signs of cardiac failure as a result of the transplanted tissue. There are some deleterious side effects of cyclosporine A, principally related to kidney function, but the drug can now be synthesized, and its nephrotoxic properties should soon be deleted from sister compounds.

The developing technology for organ preservation has widened the pool of donors. Hearts can not be transported probably up to 2,000 miles with every expectation that the transplant will perform satisfactorily immediately. Further work is progressing nicely in this area of research, and the day will come when hearts can be preserved to the same temporal limits enjoyed now by renal and liver grafts.

Last year, in the United States alone, approximately 100 patients underwent cardiac transplantation, 30 at Stanford. The 1-year survival rate now stands at 80 percent, and fully 90 percent of all patients having heart transplants at Stanford leave the hospital in stable condition. This statistic contrasts markedly with the 22 percent 1-year survival 15 years ago, which was the first year of clinical heart transplantation at Stanford University.

Of 260 patients having cardiac transplants, 106 at Stanford are alive and well now between 13½ years and 2 weeks following the procedure. Suffice it to say that transplantation of the heart is now on the same therapeutic footing as kidney transplants. Medical centers all over the world are re-entering the field, and many clinics are producing results comparable to our own. This year, the number of transplants should at least double last year's total with further expansion to be expected later in the decade.

The hospital cost for a patient having heart transplantation at Stanford is roughly twice that for a standard open heart surgical procedure at Stanford. No professional fees have ever been charged for any transplantation procedure, either heart or heart-lung.

Donor costs average $3,000 and are independent of whether the donor is an on-site donor or in another hospital.

In the past, transplantation of the lungs have produced the most dismal results of any kind of organ transplantation. Of 38 unilateral lung transplants, no patient lived as long as 10 months, and most patients died within a few days to a few weeks after the procedure. Presently at Stanford, 8 of 11 patients having transplantation of both lungs along with the heart are alive and well, out of the hospital and fully rehabilitated 2 months to 2 years after the transplant. This complete turnaround in clinical results derives from the concept of using the heart as the monitor of immunologic events surrounding the transplanted cardiopulmonary axis. Actual biopsy of the heart reveals precisely the status of the lungs with respect to the host's immune reactivity, since the heart and lungs are rejected pari passus.

Irrespective of any conceivable advance in artificial organs, heart-lung transplantation is here to stay. The concept of a totally implantable artificial heart with an inexhaustible, noiseless, non-heat-producing energy source is one that we all respect, but its realization is decades away. And anything man-made that could substitute for the entire cardiopulmonary axis is simply beyond conceptualization. The early clinical results of heart-lung transplantation at Stanford are so gratifying that other centers are almost certain to develop their own programs. Twenty-one such transplants have now been done worldwide, and next year we will see perhaps another fifty.

California has a State law that declares the individual dead if the brain is dead. The law wisely does not attempt to define brain death, but it does consider the difference between brain injury, even severe injury, and brain death. There are in use sophisticated techniques for maintaining the function of other vital organs in brain-dead individuals for extended periods of time.

At the University of California in San Francisco recently, a 27-year-old brain-dead pregnant woman was maintained on a ventilator with intravenous feedings for 2 months, with the delivery of a 3-pound, 31 weeks gestation live baby; life after death, as it were. This remarkable case illustrates prolonged survival of the heart and lungs in a brain-dead patient when appropriate care is given to protect those organs from infection, atelectasis or collapse of the lungs, and undue loss of circulatory volume.

At the outset of heart transplantation, many potential heart donors were lost owing to medical and nursing neglect. Why put so much effort into the care of patients who were already dead? Through various educational programs and seminars where the results of transplantation of the heard and of the kidneys were discussed, intensive care units in most hospitals began to make the necessary maneuvers to keep organs in transplantable condition. The heart is the most prodigious consumer of oxygen of any organ in the body, so its care in the potential donor must be precise and thorough. Lungs are even more difficult to maintain in transplantable health. Teaching programs are now just starting in the San Francisco Bay area to acquaint intensive unit personnel in certain key hospitals with the essentials of pulmonary care in the potential heart-lung donor.

With respect to donors, there are, of course, certain age restrictions. The youngest donor to be used for heart transplantation at Stanford was 12 years, the oldest 51. Arteriograms are needed in any donor greater than 35 years of age to rule out coronary artery disease. In the State of California alone, there are 5,000 traffic deaths each year. Not all or even a third of these are suitable for donors, but the point is there are many more donors than are now being utilized.

The public is, however, increasingly aware of the possibilities of organ donation. In California, there are many renal transplant programs, and we collaborate with these centers to an extent that the usual wait for a heart is no more than a few weeks. The delay for an adequate heart-lung donor is much longer, but we hope to improve the situation by our outreach training programs for intensive care unit personnel.

In summary, then, transplantation of the heart is a proven therapeutic intervention with a 5-year survival of at least 50 percent, and 1-year survival rate that approaches 80 percent. Physicians taking care of brain-dead individuals and the families of brain-dead patients are becoming increasingly aware of the need for transplantable organs. Additional programs are being inaugurated to train health care personnel in the maintenance of various organs in transplantable condition.

While there may be some future application for the artificial heart as an interim device before transplantation, there is no such mechanical substitute for the lungs, and the early results of transplantation of the heart along with both lungs are even better than for transplantation of the heart alone. So it is clear that the need for adequate identification and care of donors is of tremendous and ever-increasing importance.

Thank you.

Mr. GORE. Thank you very much, Dr. Shumway.

We will hold up on questions until the whole panel has completed its testimony.

[The prepared statement of Dr. Shumway follows:]

HEART AND HEART-LUNG TRANSPLANTATION

Norman E. Shumway, MD, PhD
Professor and Chairman, Department of Cardiovascular Surgery
Stanford University School of Medicine
Stanford, California

FIRST, LET ME MAKE A FEW GENERAL COMMENTS REGARDING THE PRESENT STATUS OF HEART AND HEART-LUNG TRANSPLANTATION. I WOULD LIKE THEN TO FOCUS ON THE SOMEWHAT SPECIAL PROBLEMS ASSOCIATED WITH HEART AND HEART-LUNG DONORS.

DURING THE LAST DECADE TREMENDOUS PROGRESS HAS BEEN MADE IN THE SCIENCE AND PRACTICE OF TRANSPLANTATION. NEW DRUGS HAVE BECOME AVAILABLE TO CONTROL MORE EFFECTIVELY THE IMMUNE RESPONSE TO TRANSPLANTED TISSUE. AS A MATTER OF FACT, SINCE WE BEGAN THE USE OF CYCLOSPORIN A IN DECEMBER OF 1980, THERE HAS NOT BEEN A SINGLE INSTANCE OF CLINICALLY DIAGNOSABLE REJECTION OF THE ALLOGRAFTED HEART. TRUE, THERE ARE SOME DELETERIOUS SIDE EFFECTS OF CYCLOSPORIN A, PRINCIPALLY RELATED TO KIDNEY FUNCTION, BUT THE DRUG CAN NOW BE SYNTHESIZED, AND ITS NEPHROTOXIC PROPERTIES SHOULD SOON BE DELETED FROM SISTER COMPOUNDS.

THE DEVELOPING TECHNOLOGY FOR ORGAN PRESERVATION HAS WIDENED THE POOL OF DONORS. HEARTS CAN NOW BE TRANSPORTED PROBABLY UP TO 2000 MILES WITH EVERY EXPECTATION THAT THE TRANSPLANT WILL PERFORM SATISFACTORILY IMMEDIATELY. FURTHER WORK IS PROGRESSING NICELY IN THIS AREA OF RESEARCH, AND THE DAY WILL COME WHEN HEARTS CAN BE PRESERVED TO THE SAME TEMPORAL LIMITS ENJOYED BY RENAL AND LIVER GRAFTS.

LAST YEAR IN THE UNITED STATES ALONE APPROXIMATELY 100 PATIENTS UNDERWENT CARDIAC TRANSPLANTATION, 30 AT STANFORD. THE ONE-YEAR SURVIVAL RATE NOW STANDS AT 80 PERCENT, AND FULLY 90 PERCENT OF ALL PATIENTS HAVING HEART TRANSPLANTATION AT STANFORD LEAVE THE HOSPITAL IN

STABLE CONDITION. THIS STATISTIC CONTRASTS MARKEDLY WITH THE 22 PERCENT ONE-YEAR SURVIVAL 15 YEARS AGO, THE FIRST YEAR OF CLINICAL HEART TRANSPLANTATION AT STANFORD UNIVERSITY.

ONE HUNDRED AND SIX OF 260 PATIENTS HAVING CARDIAC TRANSPLANTS AT STANFORD ARE ALIVE AND WELL BETWEEN 13-1/2 YEARS AND TWO WEEKS FOLLOWING THE PROCEDURE. SUFFICE IT TO SAY THAT TRANSPLANTATION OF THE HEART IS NOW ON THE SAME THERAPEUTIC FOOTING AS KIDNEY TRANSPLANTATION. MEDICAL CENTERS ALL OVER THE WORLD ARE REENTERING THE FIELD, AND MANY CLINICS ARE PRODUCING RESULTS COMPARABLE TO OUR OWN. THIS YEAR THE NUMBER OF TRANSPLANTS SHOULD AT LEAST DOUBLE LAST YEAR'S TOTAL WITH FURTHER EXPANSION TO BE EXPECTED LATER IN THE DECADE.

THE HOSPITAL COST FOR A PATIENT HAVING HEART TRANSPLANTATION AT STANFORD IS ROUGHLY TWICE THAT FOR A STANDARD OPEN HEART SURGICAL PROCEDURE AT STANFORD. NO PROFESSIONAL FEES HAVE EVER BEEN CHARGED FOR ANY TRANSPLANTATION PROCEDURE, EITHER HEART OR HEART-LUNG. DONOR COSTS AVERAGE $3000 AND ARE INDEPENDENT OF WHETHER THE DONOR IS AN ON-SITE DONOR OR IN ANOTHER HOSPITAL.

IN THE PAST, TRANSPLANTATION OF THE LUNGS, OF PULMONARY TISSUE, HAS PRODUCED THE MOST DISMAL RESULTS OF ANY KIND OF ORGAN TRANSPLANTATION. OF 38 UNILATERAL LUNG TRANSPLANTS NO PATIENT LIVED AS LONG AS TEN MONTHS, AND MOST PATIENTS DIED WITHIN A FEW DAYS TO A FEW WEEKS AFTER THE PROCEDURE. PRESENTLY AT STANFORD EIGHT OF ELEVEN PATIENTS HAVING TRANSPLANTATION OF BOTH LUNGS ALONG WITH THE HEART ARE ALIVE AND WELL, OUT OF THE HOSPITAL AND FULLY REHABILITATED TWO MONTHS TO TWO YEARS AFTER THE TRANSPLANT. THIS COMPLETE TURNAROUND IN CLINICAL RESULTS DERIVES FROM THE CONCEPT OF USING THE HEART AS THE MONITOR OF IMMUNOLOGIC EVENTS SURROUNDING THE TRANSPLANTED CARDIOPULMONARY AXIS.

ACTUAL BIOPSY OF THE HEART REVEALS PRECISELY THE STATUS OF THE LUNGS WITH RESPECT TO THE HOST'S IMMUNE REACTIVITY, SINCE THE HEART AND LUNGS ARE REJECTED PARI PASSUS.

IRRESPECTIVE OF ANY CONCEIVABLE ADVANCE IN ARTIFICIAL ORGANS, HEART-LUNG TRANSPLANTATION IS HERE TO STAY. THE CONCEPT OF A TOTALLY IMPLANTABLE ARTIFICIAL HEART WITH AN INEXHAUSTIBLE, NOISELESS, NON-HEAT-PRODUCING ENERGY SOURCE IS ONE THAT MUST BE RESPECTED, BUT ITS REALIZATION IS DECADES AWAY. AND ANYTHING MAN-MADE THAT COULD SUBSTITUTE FOR THE ENTIRE CARDIOPULMONARY AXIS IS SIMPLY BEYOND CONCEPTUALIZATION. THE EARLY CLINICAL RESULTS OF HEART-LUNG TRANSPLANTATION AT STANFORD ARE SO GRATIFYING THAT OTHER CENTERS ARE ALMOST CERTAIN TO DEVELOP THEIR OWN PROGRAMS. TWENTY SUCH TRANSPLANTS HAVE NOW BEEN DONE WORLDWIDE, AND NEXT YEAR WILL SEE PERHAPS ANOTHER FIFTY.

CALIFORNIA HAS A STATE LAW THAT DECLARES THE INDIVIDUAL DEAD IF THE BRAIN IS DEAD. THE LAW WISELY DOES NOT ATTEMPT TO DEFINE BRAIN DEATH, BUT IT DOES CONSIDER THE DIFFERENCE BETWEEN BRAIN INJURY, EVEN SEVERE INJURY, AND BRAIN DEATH. THERE ARE IN USE SOPHISTICATED TECHNIQUES FOR MAINTAINING THE FUNCTION OF OTHER VITAL ORGANS IN BRAIN-DEAD INDIVIDUALS FOR EXTENDED PERIODS OF TIME. ONE MIGHT IN POINT OF FACT ALMOST CONTEND THAT THE DEFINITION OF DEATH TODAY MUST BE MADE IN TERMS OF AN ORGAN SYSTEM THAT CANNOT BE TRANSPLANTED, I.E., THE CENTRAL NERVOUS SYSTEM. OF COURSE PSYCHIATRISTS MIGHT TELL YOU THEY HAVE BEEN TRANSPLANTING THE BRAIN EVER SINCE THE DAYS OF SIGMUND FREUD! AT THE UNIVERSITY OF CALIFORNIA HOSPITAL IN SAN FRANCISCO RECENTLY, A 27-YEAR-OLD BRAIN-DEAD PREGNANT WOMAN WAS MAINTAINED ON A VENTILATOR WITH PARENTERAL OR INTRAVENOUS FEEDINGS FOR TWO MONTHS, WITH THE DELIVERY OF A 3-POUND, 31 WEEKS GESTATION LIVE BABY; LIFE AFTER DEATH, AS IT WERE. THIS

REMARKABLE CASE ILLUSTRATES PROLONGED SURVIVAL OF THE HEART AND LUNGS IN A BRAIN-DEAD PATIENT WHEN APPROPRIATE CARE IS GIVEN TO PROTECT THOSE ORGANS FROM INFECTION, ATELECTASIS OR COLLAPSE OF THE LUNGS, AND UNDUE LOSS OF CIRCULATORY VOLUME.

AT THE OUTSET OF HEART TRANSPLANTATION, MANY POTENTIAL HEART DONORS WERE LOST OWING TO MEDICAL AND NURSING NEGLECT. WHY PUT SO MUCH EFFORT INTO THE CARE OF PATIENTS WHO WERE ALREADY DEAD? THROUGH VARIOUS EDUCATIONAL PROGRAMS AND SEMINARS WHERE THE RESULTS OF TRANSPLANTATION OF THE HEART, AND OF KIDNEYS TOO, WERE DISCUSSED, INTENSIVE CARE UNITS IN MOST HOSPITALS BEGAN TO MAKE THE NECESSARY MANEUVERS TO KEEP ORGANS IN TRANSPLANTABLE CONDITION. THE HEART IS THE MOST PRODIGIOUS CONSUMER OF OXYGEN OF ANY ORGAN IN THE BODY, SO ITS CARE IN THE POTENTIAL DONOR MUST BE PRECISE AND THOROUGH. LUNGS ARE EVEN MORE DIFFICULT TO MAINTAIN IN TRANSPLANTABLE HEALTH. TEACHING PROGRAMS ARE NOW JUST STARTING IN THE SAN FRANCISCO BAY AREA TO ACQUAINT INTENSIVE CARE UNIT PERSONNEL IN CERTAIN KEY HOSPITALS WITH THE ESSENTIALS OF PULMONARY CARE IN THE POTENTIAL HEART-LUNG DONOR.

WITH RESPECT TO DONORS THERE ARE OF COURSE CERTAIN AGE RESTRICTIONS. THE YOUNGEST DONOR TO BE USED FOR HEART TRANSPLANTATION AT STANFORD WAS 12 YEARS OLD, THE OLDEST 51. ARTERIOGRAMS ARE NEEDED IN ANY DONOR GREATER THAN 35 YEARS OF AGE TO RULE OUT CORONARY ARTERY DISEASE. IN THE STATE OF CALIFORNIA ALONE THERE ARE 5,000 TRAFFIC DEATHS EACH YEAR. NOT ALL OR EVEN A THIRD ARE SUITABLE FOR DONORS, BUT THE POINT IS THERE ARE MANY DONORS THAT ARE NOT NOW BEING UTILIZED.

THE PUBLIC IS, HOWEVER, INCREASINGLY AWARE OF THE POSSIBILITIES OF ORGAN DONATION. IN CALIFORNIA THERE ARE MANY RENAL TRANSPLANT PROGRAMS, AND WE COLLABORATE WITH THESE CENTERS TO AN EXTENT THAT THE USUAL WAIT

FOR A HEART IS NO MORE THAN A FEW WEEKS. THE DELAY FOR AN ADEQUATE HEART-LUNG DONOR IS MUCH LONGER, BUT WE HOPE TO IMPROVE THE SITUATION BY OUR OUTREACH TRAINING PROGRAMS FOR INTENSIVE CARE UNIT PERSONNEL.

IN SUMMARY, THEN, TRANSPLANTATION OF THE HEART IS A PROVEN THERAPEUTIC INTERVENTION WITH A FIVE-YEAR SURVIVAL OF AT LEAST 50% AND A ONE-YEAR SURVIVAL THAT APPROACHES 80%. PHYSICIANS TAKING CARE OF BRAIN-DEAD INDIVIDUALS AND THE FAMILIES OF BRAIN-DEAD PATIENTS ARE BECOMING INCREASINGLY AWARE OF THE NEED FOR TRANSPLANTABLE ORGANS. ADDITIONAL PROGRAMS ARE BEING INAUGURATED TO TRAIN HEALTH CARE PERSONNEL IN THE MAINTENANCE OF VARIOUS ORGANS IN TRANSPLANTABLE CONDITION.

WHILE THERE MAY BE SOME FUTURE APPLICATION FOR THE ARTIFICIAL HEART AS AN INTERIM DEVICE BEFORE TRANSPLANTATION, THERE IS NO SUCH MECHANICAL SUBSTITUTE FOR THE LUNGS, AND THE EARLY RESULTS OF TRANSPLANTATION OF THE HEART ALONG WITH BOTH LUNGS ARE EVEN BETTER THAN FOR TRANSPLANTATION OF THE HEART ALONE, SO IT IS CLEAR THAT THE NEED FOR ADEQUATE IDENTIFICATION AND CARE OF DONORS IS OF TREMENDOUS AND INCREASING IMPORTANCE.

Mr. **Gore**. Dr. Starzl, I have already told you how much we appreciate your being here. It really is an honor. Please proceed with your testimony.

Dr. **Starzl**. Thank you, Mr. Gore.

I provided to the subcommittee copies of a written statement which I won't read because I might fall asleep. What it really did was to provide a summary for you of the developments in transplantation, what has made this field possible, and it has really emphasized the kidney, which is the organ that has permitted the development of the antirejection programs.

I was saddened to hear from Mr. Skeen of somebody who died in 1962, because that was the year when the great explosion occurred with first use of Imuran and Prednisone together. And then the subsequent landmarks have been 1966, which is the year that triple drug therapy with antilymphocyte globulin [ALG] was introduced in which ALG plus the other two agents was given in triple drug therapy, and then, recently, as you heard, the cyclosporine-steroid story.

Liver transplantation was first carried out, to answer a question that you posed before, Congresswoman Schneider, in 1963, almost exactly 20 years ago, the 1st of March. It is a procedure that has prolonged life for many people, going back a number of years. The oldest survival now is in the 14th postoperative year. I was a little surprised this morning to see a young handsome teenage boy down there, that redheaded boy at the end, who was treated 9 years ago last Thanksgiving day. He broke up all of the Thanksgiving parties going on.

Just as a parenthetical aside, you can't control the supply of donors. I am sure Dr. Shumway has had the same experience. We did Danny—who is from the Washington area—and then followed him immediately with a young woman from San Francisco who has subsequently had two children and who was sponsored by CHAMPUS. CHAMPUS paid for this procedure. By the way, the San Francisco lady, the CHAMPUS symbol, is still living and still perfectly well. I think she is pregnant for the third time. Maybe that is what induced them—CHAMPUS—to stop, I don't know.

There are surgeons around the country, and many of them—Jim Williams, whom you heard already, is a good example—who are fully qualified to carry out liver transplantation. In fact, the Tennessee group is an unusually good one because there are three people down there who trained with us. One, many years ago, is Lou Britt. Tom Peters spent 1½ years with us a few years ago. And then there was Jim Williams, whom you heard today.

But why haven't they been able to function? The reason has been this very problem of financing the cost of the enterprise. This is really a big tragedy, because we have well-trained people capable of carrying out liver transplantations all over the United States who can't move forward. In fact, the people whom I have trained have been able to function better and in the Far East and Europe than they have in the United States.

I would like to look at the question of cost. It was an outrage to Captain Broderick that a price tag should be put on his daughter. I would like to look at the situation a little bit differently for those who are only interested in money. Captain Broderick's child is in the water. If he went into the sea and his rescue would cost $1 million—we do it readily. He can't understand why his daughter who is down can't be bailed out. But for those who don't believe that kind of sentimental approach, there are studies out—one of them is in process at the NIH which shows how much it costs to die from end-stage liver disease.

I spoke to one of the officials at the NIH, whose name I think I shouldn't disclose publicly because it would be a breech of confidence, who told me that, to survive for 1 year after the first hemmorrhage from esophogeal varices—which is one of the things that happen to people with end-stage liver disease—the cost of survival for insurance carriers or for the Government, or for whoever is paying that bill, is $260,000, five times as much as a transplant.

In the American Journal of Surgery, in early 1981, there was a study from Boston indicating that the cost of taking care of a patient who has bled the first time from an esophageal varix is $57,000 if any kind of operation is needed. That is $57,000 down a therapeutic cul-de-sac, because patients like that have no place to go except the grave. The point is that it costs a lot to bury them, far more—and perhaps as much as five times more—as it would cost to save them.

What we are really getting to, I think, to crib a phrase that you already used, we don't have the mechanisms of action in place. Jim Williams, and perhaps some of the other people, with understandable bitterness have described how a ruling—not law—but some kind of a guideline ruling by the medicare agency that liver transplantation is experimental has been used as a refuge by cost-conscious HMO's and apparently by other Government agencies such as CHAMPUS to avoid this responsibility. I think you are perfectly correct in saying that there is powerful action being taken by the White House to try to do something about that, as well as by people in legislative bodies of both parties, to try to do something about that situation.

Incidentally, I know for a fact that the same thing applies to cardiac transplantation. The field has been distorted, or at least caused to remain atrophic, because the same mechanism of denial of payments for heart transplants has been used, it is experimental. That means that all of the Federal agencies deny payment on those grounds. But the real problem comes when the cost-conscious HMO's, the third-party private carriers say, "Well, look, the government has said it is experimental and we will not will not pay because, if the Government says so, that must be so."

Mr. GORE. Dr. Starzl, let me interrupt you to say that it could be changed administratively by the White House and by the administrators of these agencies. I might note for the record that, when we started calling witnesses for this hearing, not long afterwards, we heard back from NIH that they were going to schedule in June a National Institutes of Health consensus development conference to try to change this.

I think we have a bioethical imperative to change it even before then. For patients in the condition of Captain Broderick's daughter, we shouldn't have to wait for a conference 2 months from now. She may not make it that long.

Excuse me for interrupting.

Dr. **Starzl.** I am glad you did. I think it is important.

People from all levels and from many agencies have been really anxious to have the consensus development conference go forward. I am personally anxious to have one go forward for hearts. I was with your people, as you know, Norm Shumway, on that white paper conference that developed a position in 1980, which actually almost had the opposite effect of what we had hoped. It almost stultified the growth of cardiac transplantation instead of helping it.

So I think this other avenue, which is really an effort to assure third-party insurance carriers that this is a service, is probably a better one rather than depending on government funding.

But the point that I was trying to make is that well-meaning people in government can sometimes be the means by which a shield, is created which prevents other private agencies from taking up the burden.

The same thing applies to organ procurement. That is the point that I really want to get to. As I am sure you will verify, there is no visible means of support to get extra-renal organs. There is no way to pay for hearts. There is no way to pay for livers. There is no way to pay for pancreases or heart-lungs.

What we have done—and because some of us, Mel Williams and I, have been in the kidney field for 20 years—is to call back old debts from many people and to develop networks, professional networks, just talking amongst ourselves and we have been able to engraft our efforts upon existing renal programs which are funded from Federal sources.

Here, also, there can be the stultifying effect of Government, because—and I think I got this information from Mel Williams about a year ago, there was a letter sent or some kind of a for-your-information document sent out from Aetna, which is the carrier for the end-stage renal procurement program. It was a kind of a warning to the transplant coordinators and to the renal transplant surgeons who were out getting organs. It had some flash phrases, including the fact that they had to understand that if they collaborated with Norm Shumway and with me and others, there was no liability coverage, for these extra-renal organs. And second, that they were not covered for the expenses of the other organs.

There was another thing, too, that was very important. I think it says something about the courage of the transplant coordinators, whom you will be hearing from. They lost their personal liability coverage. So as they ran around the country in small planes, if something happened to them in the course of going out for livers or hearts, they were not covered. This was all stated in the document that went around. It really had a chilling effect on the transplant coordinators.

Mr. **Gore.** Dr. Starzl, without objection, I would like to put that document to which you refer in the record at this point.

I would like to clarify the record that, when you refer to extra-renal organs and the problem you are discussing, you are talking about a situation where kidneys are harvested from a donor, and the other organs such as the heart, the liver, and the lungs, are not retrieved for those who need them sometimes because there is no funding mechanism for that retrieval.

Dr. **Starzl**. Or because there is resistance from people who fear the consequences.

Mr. **Gore**. Including the lack of insurance and the warning from the carrier of the national kidney program that they will lose their insurance coverage if they retrieve other organs in addition to the kidney.

Dr. **Starzl**. There was a such a document, yes. I think that is an accurate summary. We can easily get that for you.

Mr. **Gore**. It is in the record at this point.

[The information follows:]

medicare bulletin

OP-81-6 --- October 1, 1981

PRODUCT LIABILITY AND MALPRACTICE COVERAGE

PRIMARY INTEREST: ORGAN PROCUREMENT AGENCIES

In June of this year Aetna informed all IOPAs by letter of a potentially serious problem concerning the procurement of organs other than kidneys. Our concern was with the costs of a lawsuit which originated from the OPA's involvement in procuring organs other than kidneys. Hopefully, you have reviewed your specific situation with your Board of Directors, Attorney, and Insurance Agent.

The Health Care Financing Administration - End Stage Renal Disease has given us a policy decision on this issue. The following paragraphs are their reply.

If the OPA has product liability and malpractice coverage the Medicare Program will reimburse the cost of this insurance. If you are named a party to a lawsuit which resulted from the retrieval of tissue or an organ other than a kidney the costs of legal fees, settlements and related costs would not be reimbursed by Medicare.

If the OPA does not have product liability and malpractice coverage the Medicare Program will reimburse the OPA for legal fees, settlements and related costs for claims arising from the retrieval of kidneys. This does not include physician professional coverage for the procurement of the kidney. However, should a lawsuit develop from activity performed in the retrieval of any tissue or organ that is not a kidney, the Medicare Program will reimburse none of these expenses.

Continued on the back

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Dr. **Starzl.** I think that the reason that things have gone forward as they have—and I am sure that Norm Shumway will verify this as well—the reason that things went forward is that kidney transplanters who have a big network, and maybe especially the transplant coordinators, made this a crusade. The transplant coordinators have discussed it at their meetings. They have asked me and others, and we have willingly gone to participate, in their national meetings and to tell them how we can put aside some of these objections to the procurement of extra-renal organs.

As a matter of fact, as you have heard from the coordinator, Mr. Hall, from Tennessee, they—the coordinators—have themselves set up this 24-Donor System which is an 800 number. This donor that you heard about this morning came from that 800 system. Mr. Don Denny, whom you will be talking to later, set up the 24-Donor System. It is the most effective system that I know of. It covers the country.

Solutions—I think if the barriers were removed that are imposed by the existing guidelines, it would be an enormous step forward. I think we ought to face squarely the fact that this is a new epoc. What you said this morning, Norm, and what we have both said in print, is that the decade of the 1980's is going to be remembered, I think, as the time when transplantation really came to full fruition and realizes the promise that did not materialize in the 1960's when we all started in transplantation.

If we recognize that and if we remove these guideline barriers to the implementation of programs—the programs will spring up. I think there will be many liver programs if this consensus conference goes forward positively, and I am guessing 20 to 30. We are very busy training people, or refreshing people who are already trained, so that they can set up programs. I won't embarrass the centers by mentioning their names, but there must be already around 12 that are ready to go.

We have to carry out intensive education efforts, and we are really trying to do that through journals. I think we have to reach the physicians. Mr. Denny wrote, at their request, an editorial about pediatric donor procurement for the Journal of Pediatrics which will be coming out soon. But maybe especially we have to educate lay people.

The figures that we have heard about, the low percentage of donations amongst the black population—it is tragic if it is true. As we heard last week at another meeting, the incidence of renal disease amongst the black population is higher, not lower, than in the population in general, so there is a greater need for organs, not less. Thus, there should be a stronger incentive than normal to create attractive donor programs amongst blacks.

The 24-Donor System which I have mentioned, may not be the final prototype, but it is a good prototype to start from because it just started on its own in response to need.

I think to develop some way of bringing the extra-renal organs on a level of parity with the kidney is quite important. The kidney procurement programs are funded by the end-stage renal disease program as a free-standing program and, somehow, it needs to be written into law, I think, that other organs are needed and are perhaps an even more priceless resource.

Mr. **Gore.** Thank you very much, Dr. Starzl. We will hold up on questions.

[The prepared statement of Dr. Starzl follows:]

TESTIMONY:

THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

Organ transplantation including transplantation of the kidney has been a realistic possibility only since 1962 when multiple agent therapy was first standardized. The first breakthrough was in 1962 with the combined use of two drugs called Imuran and Prednisone, to which a third agent called antilymphocyte globulin - - or ALG - - was added in 1966.

Using the double drug or triple drug combinations, acceptable results became possible with renal transplantation between family members. In contrast, the national average for one-year kidney survival after renal transplantation using cadaver donors has only been about 50 percent. Even such limited successes have depended upon the use of high doses of steroids. The steroids have such severe side effects that many centers exclude older patients from consideration for kidney transplantation, and in some of the European contries no one over the age of 60 is admitted for consideration.

Obviously, the transplantation of other organs including those of the GI tract - - the liver, intestine, and pancreas - - but also including the heart and lung must be from cadaver donors. Thus, the same limitations imposed by suboptimal drug treatment have inhibited the development of transplantation of these other organs, including those of the GI tract. For almost 20 years, there seemed no way out of the dilemma. The drugs being used were, on the one hand, unreliable in preventing rejection, and on the other excessively dangerous.

In 1976, Dr. Jean Borel, a basic scientist working at the Sandoz Corporation in Basel, Switzerland, discovered and characterized a new immunosuppressive drug called cyclosporine. This drug was released for limited clinical trial in Britain in 1978, and in 1979 it became available in the United States at two centers, including ours.

We realized almost from the outset with cyclosporine that prednisone could be used in much smaller quantities than at any time in the past, that rejection control was better, and with a smaller risk to the patients.

Even during our learning phase (in 1980) the one - year cadaver kidney survival rose to 80 percent. Our subsequent experience at the University of Pittsburgh (in 1981) resulted in a one - year cadaver kidney graft survival of greater that 90 percent. The patient mortality in the first year of our Pittsburgh trials was less than one percent.

Almost from the beginning of cyclosporine use, many of the contraindications to kidney transplantation have been softened so that people previously excluded because of advanced age or other disease have now been accepted as candidates.

It was natural to extend this major advance in therapy to recipients of other organs. The first trials with liver transplantations under cyclosporine were begun in early 1980, 3 years ago. The one - year liver graft and patients survival was twice that achievable in previous times, ranging 65 - 70%. These results have been so encouraging that at the Unversity of Pittsburgh liver transplantation is now considered a service as opposed to an experimental procedure. We carried out 82 liver transplantations in 1982, almost four times the yearly number ever previously possible in our nearly 20 years of work in this field. In 1983, we expect to do more than 100.

The cyclosporine - steroid combination has also been used since early 1981 both at Stanford University and at the University of Pittsburgh for heart transplantation.

The implication of these improvements in drug therapy are apt to have a profound effect on health care delivery as this applies to transplantation. In renal transplantation, the interface between dialysis and transplantation will be drastically altered when cyclosporine becomes generally available, and this with a great cost savings to the tax payers who pay for the $2 billion a year end - stage renal disease program.

The wider application of transplantation techniques to people with failure of the liver, heart, pancreas, intestine, and other organs is a clinical reality today and now. It is likely that cost savings can be engendered here also as well as provision of better health care. These developments will be dependent on improvements of cadaveric organ procurement.

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Evolution of Liver Transplantation

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Two general kinds of liver transplantation have been attempted clinically. With one approach, the host liver is removed and replaced with a homograft (orthotopic liver transplantation); alternatively, an extra liver is inserted at an ectopic site (auxiliary homotransplantation). This review concerns only orthotopic liver transplantation.

The first effort to replace a human liver was made at the University of Colorado on March 1, 1963. That patient died as did four others during the next 7 months (1, 2) (Table 1). In September, 1963 and January, 1964, other unsuccessful attempts at liver replacement were made in Boston (3) and Paris (4) (Table 1). The first clinical trials were not frivolously undertaken. Members of the Boston and Denver teams had developed techniques for liver replacement in dogs in the late 1950s and, in both laboratories, research on liver transplantation had been continuously performed for more than 4 years.

Nevertheless, the consecutive failures in three institutions halted all clinical trials until our sixth and seventh equally unsuccessful attempts in October, 1966 and May, 1967. Finally, on July 23, 1967, the first extended survival of a human recipient was achieved (5). The patient, a 1½-year-old girl, lived for more than 13 months before dying of metastases from the hepatocellular carcinoma for which she had been treated. From then until the first week of May, 1982, we have treated 230 more patients, 163 at the University of Colorado and 67 at the University Health Center of Pittsburgh for a total of 237. The yearly frequency of transplantation throughout our experience is shown in Figure 1. The highest number of 30 was reached in 1981; the number of new cases in 1982 is projected at between 60 and 80.

A signal event in the development of orthotopic liver transplantation occurred on May 2, 1968 when Calne and Williams of the University Hospital at Cambridge and the King's College in London, respectively, treated the first patient in their program (6, 7) which had since generated more than 125 well-studied cases. Calne's contributions in experimental renal transplantation has been a major factor in the early development (8) of chemical immunosuppression, without which transplantation of any organ was not realistic until 2 decades ago. The fact that both men had the personal qualities to be able to accept defeat or victory with equal grace was fortunate since failure was the dominant theme with all such efforts until recent times.

In this review, emphasis will be placed on the more than 350 cases in these two series. However, between 1968 and 1978, other single attempts or small series were reported from Boston (9, 10), Los Angeles (11), Montreal (12), Bonn (13, 14), Sao Paulo (15), Calgary (16), New York City (17), Richmond (18), Minneapolis (19), Manchester (20), and Oslo (21). It is probable that these documented cases were a minority of those attempted in that decade, exclusive of the English and Colorado series. Since 1978, programs have been reopened or started new from which important information can be expected. In the United States, clinical liver transplantation programs are active at the University of Minnesota (J. S. Najarian, unpublished observations) and the University of Tennessee (J. W. Williams, unpublished observations). Series of six or more cases each have been reported or are in preparation from Holland (22), East Germany (23), West Germany (24, 25), France (26), and the Republic of China (H. Q. Hong, unpublished observations). The number of cases in the West German series (25) has passed 50, but the results have not yet been published in detail.

EARLY EXPERIMENTAL BACKGROUND

The first known efforts at experimental orthotopic transplantation of the liver were made by Dr. Jack Cannon of Los Angeles (27). This report was so brief that it lacked a title, description of methods, and notation of the animal species. The animals did not survive operation.

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TABLE 1. THE FIRST TRIALS OF ORTHOTOPIC LIVER TRANSPLANTATIONS

No.	Location (ref.)	Age (yr)	Disease	Survival (days)	Main cause of death
1	Denver (1)	3	Extrahepatic biliary atresia	0	Hemorrhage
2	Denver (1)	48	Hepatocellular cancer, cirrhosis	22	Pulmonary emboli, sepsis
3	Denver (1)	68	Duct cell carcinoma	7½	Sepsis, pulmonary emboli, gastrointestinal bleeding
4	Denver (2)	52	Hepatocellular cancer, cirrhosis	6½	Pulmonary emboli, ? hepatic failure, pulmonary edema
5	Boston (3)	58	Metastatic colon carcinoma	11	Pneumonitis, liver abscesses, hepatic failure
6	Denver (2)	29	Hepatocellular cancer, cirrhosis	23	Sepsis, bile peritonitis, hepatic failure
7	Paris (4)	75	Metastatic colon carcinoma	0	Hemorrhage

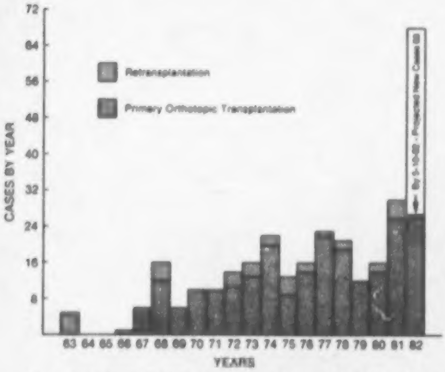

FIG. 1. Yearly number of liver transplantations at the University of Colorado (1963 to 1980) and the University of Pittsburgh (1981 to 1982). Note that retransplantation has been attempted frequently.

In June, 1958, a program of orthotopic transplantation of the canine liver was initiated at the Peter Bent Brigham Hospital under the direction of Dr. Frances D. Moore (28), and in August, our first experiments in the same species were begun at Northwestern University in Chicago (29, 30).

The technical problems of liver replacement and the features of rejection in untreated canine recipients were delineated (28–31). Eventually, using immunosuppression with azathioprine (32–34) and antilymphocyte serum or its antilymphocyte globulin (ALG) derivative (32, 35–38), chronic survival was achieved in mongrel dogs of which one lived for almost 12 years (39).

In 1965, Garnier of Paris (40) made the important observation that rejection of pig liver homografts was mild in comparison to that in dogs. Several porcine recipients lived for long times without immunosuppression. Workers in Bristol (41), Cambridge (42), and Denver (32) promptly confirmed Garnier's work. The value of the pig for transplantation research has been demonstrated frequently in the investigations of Calne and his associates.

Hundreds of significant experimental studies in various species have since been published. Review of this work will not be attempted although some of it has influenced the clinical trials as will be noted later.

NOTATIONS ABOUT SURGICAL TECHNIQUES IN HUMANS

A training period in the animal laboratories is an important preparatory step for teams planning clinical programs; however, not all of the experimental techniques are identical in humans. Our methods of orthotopic liver transplantation (1, 5, 32, 43–52) and the modifications introduced by Calne et al. (6, 47, 53) have been described.

The operation is simple in principle (Figure 2), but its execution has been exceptionally difficult because of the almost invariable debilitation of the recipients and the profoundly abnormal vascularization patterns caused by portal hypertension in endstage liver disease. Defects in clotting have been present in most cases (1, 32, 54, 55), and adhesions or other alterations secondary to previous operations are often complicating factors. With such a background, it is not surprising that the postoperative care of many patients has been an exercise in resuscitation (32). The most common difficulties have been pulmonary insufficiency (requiring mechanical ventilation for several months in some cases), renal failure with massive fluid shifts, and persistent clotting abnormalities. These problems are managed with conventional methods of intensive care with emphasis on biochemical and hemodynamic monitoring. Recovery can be expected from encephalopathy and the hepatorenal syndrome (56).

The ability to survive this critical period depends upon what has transpired in the operating room. Thus, in the following remarks, we will touch upon details of surgical technique which require reemphasis or points of view which have changed from those expressed in the past.

ORGAN PROCUREMENT AND PRESERVATION

Until 1976, techniques for preserving the liver either severely limited the acceptable time of cold ischemia or were too complicated for use in outlying hospitals (32). In 1976, simple methods that permitted reasonably long storage were developed, and clinical trials were started. We have employed an electrolyte (Collins) solution with a composition similar to that found intracellularly (57). The Cambridge-King's College team uses a plasma solution for similar cold infusion of the homograft (58). In dogs, the two methods yielded similar results (57) and allowed safe preservation for up to 12 hr. These tech-

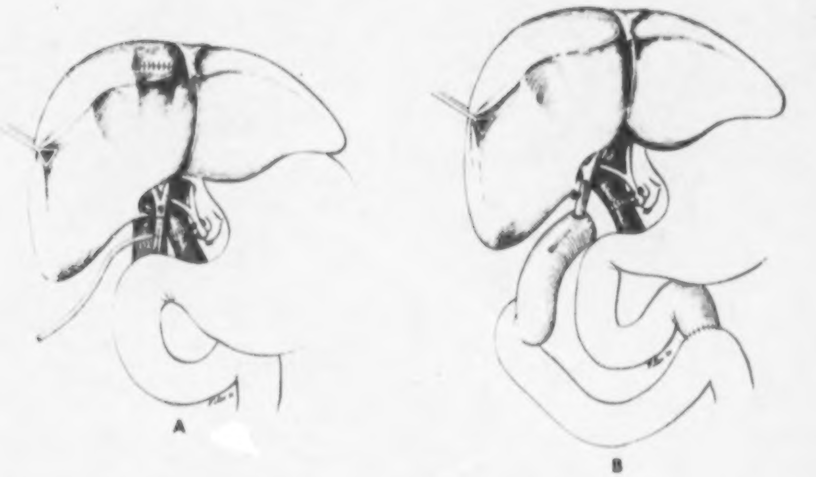

FIG. 2. Completed orthotopic liver transplantation. (A) Biliary tract reconstruction with choledochocholedochostomy. (B) Biliary tract reconstruction with choledochojejunostomy, using a Roux limb.

niques permit shipment of livers from city to city. More than two-thirds of the livers used in the Pittsburgh program have been obtained outside of the normal procurement area for this region; the longest transit being from Phoenix, Ariz. Efficient air travel arrangements are necessary; to meet this objective, several Pittsburgh corporations have donated their private jet airplanes.

Liver procurement outside of the local area has depended on cooperation with other procurement centers whose main function was previously to provide cadaveric kidneys. Fear that kidney grafts would be jeopardized by giving too high a priority to the liver has been allayed by standardization of techniques which protect all organs equally and which can be adapted to the local surgeons' wishes (59).

A midline incision is made from the pubis to the neck, and the sternum is split. The structures entering and leaving the liver are skeletonized, and the necessary preliminary steps for kidney removal are taken in the presence of an intact circulation. Then a cannula is placed through the splenic vein into the superior mesenteric vein. Rapid infusion of cold lactated Ringers' solution is used to start cooling of the liver. After 1 or 2 liters have been infused, cold Collins solution is infused through the terminal aorta at the same time as the distal thoracic aorta is cross-clamped and the cadaveric donor is exsanguinated from a cannula previously placed in the distal inferior vena cava. After removal, the cold liver is flushed with Collins solution and protected by a plastic bag which is placed in slushed ice. The performance of kidneys removed from liver donors with this technique was as good or better than has been achieved in most centers with kidney removal alone (59). With minor modifications, it has also been possible to remove the heart in addition to kidneys and liver from seven donors.

During 1981 when 30 liver homografts were used, there were 176 offers of organs. The inability to use the other 146 livers was usually because there was a disparity in size between the donor and recipient, the donor blood group was incompatible with the recipient, or Pittsburgh facilities for liver recipient care were saturated. An actual shortage of pediatric donors has existed in the 1- to 5-year age group.

RECIPIENT HEPATECTOMY

The most demanding aspect of liver transplantation is removal of the diseased native organ. The technical difficulties are usually determined by the underlying disease. The easiest situations are in patients with primary hepatic malignancies or primary biliary cirrhosis. The most difficult are in recipients with the shrunken livers of macronodular cirrhosis or in patients with multiple previous operations. On the average, hepatectomy is easier in infants and children than in adolescents and adults.

The preexisting pathologic changes often necessitate deviations from a standard plan; however, the first step is to find the hilum and dearterialize the liver which expedites hilar dissection and slows hemorrhage from the liver surface. During hilar dissection, the bile duct is transected as high as possible so that the option of duct-to-duct anastomosis is retained. The portal vein is left intact until later, in order not to aggravate the portal hypertension.

The inferior vena cava below the liver is encircled with minimal dissection. The left triangular and falciform ligaments are incised until the suprahepatic vena cava is identified. The suprahepatic vena cava is encircled to allow placement of a cross-clamp.

If all of these maneuvers are successfully executed, the liver can be isolated from the circulation by cross-clamping vessels which have been encircled but are intact. Cuffs of the suprahepatic and infrahepatic vena cava are fashioned from these vessels as the liver is removed. Sufficient infrahepatic vena cava is not difficult to obtain, but development of an adequate suprahepatic cuff may require tailoring of the vena cava which is mobilized from within the liver (46). The technique of isolating the liver and peeling it out in a bloodless state permits all residual tissue connections of the right triangular ligament and the bare areas (including the right adrenal vein) to be ligated under direct vision. The penalty with this approach is an increase (usually about 30 min) in the time of portal and vena caval cross-clamping, compared to cross-clamp time with previously described techniques (1, 32, 43).

Such cross-clamping is usually tolerated in patients with chronic disease in spite of major declines in cardiac output and variable hypotension (60): the same thing has been demonstrated in dogs subjected to chronic bile duct obstruction (61). Because of this, venous bypasses which were used in our first cases were discontinued (1, 2).

Some patients are jeopardized by the venous cross-clamping. If severe hypotension occurs after cross-clamping, Calne et al. (52, 53 recommend femoral vein-to-femoral artery bypass with an intervening oxygenator. About 10% of the English patients are so treated. One death in our last 67 patients (OT 233, Table 14), as well as a cardiac arrest which was successfully treated, may have been avoided by this precaution.

The fact that most patients recover from portal and vena inferior caval cross-clamping may have created a false impression about the safety of this practice. Usually, there is gross swelling of the intestine during the period of occlusion. Subsequently, many patients suffer from third-space fluid sequestration and postoperative renal failure. The extent to which these complex physiologic events contribute to the high perioperative mortality has not yet been delineated. For this reason, we returned in recent cases (not reported in this communication) to the practice of venous bypass which had been abandoned. Cannulas are placed into the inferior vena cava through an iliac or femoral vein and into the portal system through the open end of the transected portal vein. During the anhepatic phase, the blood is returned to a reservoir and pumped to a large vein in the neck or arm. Although this kind of bypass requires total body heparinization, bleeding has not been excessive since the "heparin effect" can be effectively reversed even in patients with severe liver disease.

BILIARY TRACT RECONSTRUCTION

Difficulties with biliary tract reconstruction were frequently lethal in our experience (43, 62, 63) and in that of the English workers (7, 49–51) until the mid-1970s. Anatomic studies by Terblanche et al. (64) suggest that deficient blood supply of the homograft duct system may be a contributory factor; however, our principal problems were due to the frequent (and inappropriate) use of cholecystoduodenostomy and to failure to diagnose the complications. The latter deficiency was resolved with the frequent use of postoperative cholangiography (Figure 3) and reoperation, if necessary. The incidence of complications has been reduced with better primary reconstruction.

We now consider duct-to-duct anastomosis to be the procedure of choice (Figure 2A). When this is not feasible, the duct is anastomosed to a Roux limb of jejunum (Figure 2B). With either technique, the homograft gallbladder is removed The results of biliary tract reconstruction in the last 67 cases are shown in Table 2. Using choledochocholedochostomy or choledochojejunostomy, an eventually satisfactory result was obtained in more than 95% of cases, although the use of an internal stent (instead of a T-tube stent) for duct-to-duct anastomoses led to a high rate of reoperation. Only two deaths resulted directly from biliary tract reconstruction.

Since 1976, Calne et al. (48) have used a technique in which the homograft common duct and gallbladder are fashioned into a common channel and anastomosed to recipient common duct or a Roux limb. Waddell and Grover (65) had described such a common channel procedure for difficult biliary tract problems.

THE QUESTION OF SPLENECTOMY

The spleen was removed in most of our early patients, in part to achieve immunodepression, but mainly to relieve hypersplenism and leukopenia which prevented the effective use of azathioprine or cyclophosphamide (32). With the advent of cyclosporin A, splenectomy was discontinued.

UNTREATABLE COMPLICATIONS

Technical complications that have occurred after liver transplantation are legion. All have been potentially treatable except for irreversible ischemic injury of the graft or early loss of its blood supply. Retransplantation is the only hope for a patient who has been given an irreversibly damaged or devascularized organ. In one of our patients, portal vein stenosis at the anastomosis was diagnosed 8 months after transplantation, and, at reoperation, the stenosis was successfully resected in spite of the fact that thrombosis had occurred requiring thrombectomy (Figure 4).

TISSUE MATCHING

The time constraints of liver preservation and urgent recipient need usually preclude systematic efforts at tis-

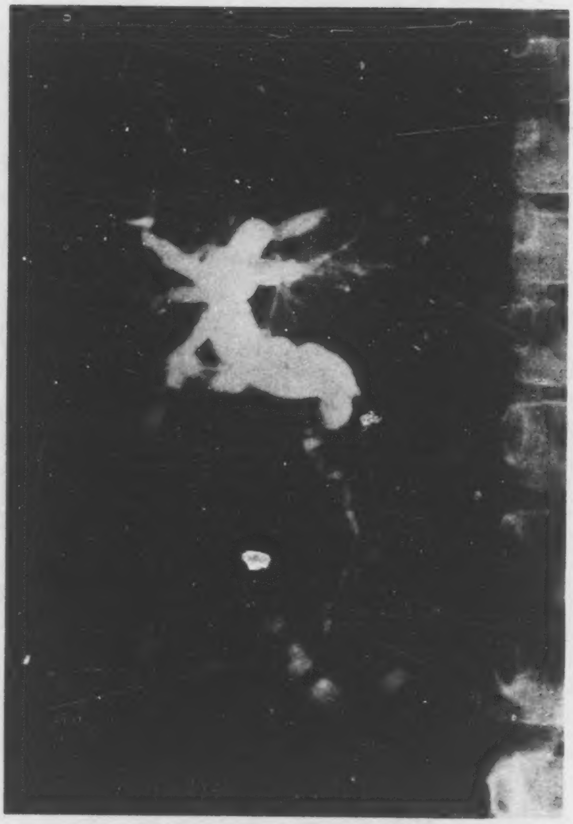

FIG. 3. Biliary obstruction 8 months after liver transplantation and a duct-to-duct reconstruction in a 10-year-old child. Note the ectasia of the recipient common duct (*arrow*). At reoperation, the graft common duct was anastomosed to a Roux limb of jejunum with a good result.

sue matching. With the random donor-recipient pairing, good matches at the A, B, and DR loci have never been obtained.

Hepatic transplantation has been performed (45, 50, 51, 66) against the recipient anti-donor T-warm antibodies which cause hyperacute rejection of kidney homografts. To our knowledge, hyperacute rejection of the liver has never been seen.

However, much more experience will be required before concluding that acceptance of "positive cross-matches" against T-warm recipient antibodies is without jeopardy. Data from the first 53 Pittsburgh cases is summarized in Table 3. Patients for whom cross-matches could not be performed or whose sera cross-matched negative with recipient cells had better results than those with cross-match positive donors. Although hyperacute rejection was not observed in the latter recipients, the postoperative courses were stormy. At least two of the livers developed delayed massive necrosis.

From experimental studies, it is known that the liver is resistant to hyperacute rejection. However, in animal xenograft models in which the recipient has performed heterospecific cytotoxins, humoral antibody rejection of the liver is merely slower than that of the kidney; the mechanisms of destruction are the same. The extent (if any) to which the outlook after clinical liver transplantation is depreciated by preformed antibodies is unknown; many liver candidates have widely reacting T-warm cytotoxic antibodies which reflect sensitization by previous blood transfusions. For the time being, we continue to treat such highly sensitized patients.

If donor-recipient ABO blood group incompatibility exists, renal grafts can be destroyed by isoagglutinins (67). Liver grafts are resistant to this kind of hyperacute

TABLE 2. PRIMARY BILE DUCT PROCEDURES AND COMPLICATIONS IN 75 LIVER TRANSPLANTATIONS ON 67 CONSECUTIVE PATIENTS IN THE CYCLOSPORIN ERA

	Choledochocholedochostomy with T-tube	Choledochocholedochostomy with internal stent	Choledochojejunostomy in Roux-en-Y with stent	Cholecystojejunostomy in Roux-en-Y	External tube drainage	Biliary reconstruction not completed (intraoperative death)
No.	25	19	20	6	3[a]	2
Success	20 (80%)	11 (58%)	18 (90%)	1 (17%)	—	—
Failure	5	8	2	5	—	—
Reoperation required	4[b]	7[b]	2	5	—	—
Cause of death	0	1	1	0	—	—
Nature of failure						
Obstruction	1	3	0	4[c]	—	—
Bile leakage	4	4	2	1	—	—
Arterioductal fistula	0	1	0	0	—	—

[a] Reconstruction was never completed in 2 of the 3 patients.

[b] One patient was treated with transhepatic dilation under X-ray control.

[c] One patient developed a large fungal liver abscess, which led to retransplantation. He is doing well with the second liver graft 1 year later.

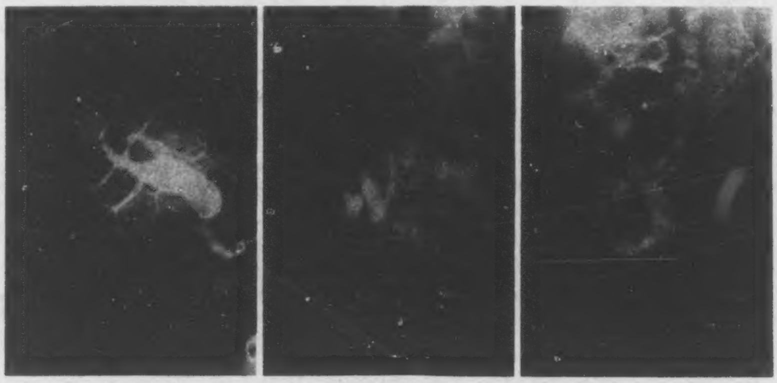

FIG. 4. (a) Stenosis of the portal vein anastomosis (*arrow*) diagnosed by transhepatic portography in the same patient whose biliary system is shown in Fig. 3. (b) Operative venogram obtained through a mesenteric vein a few days later. The obstruction was complete, and the homograft portal vein was full of thrombus. (c) Patent system after resection of the sterosis, thrombectomy, and reanastomosis.

TABLE 3. INFLUENCE OF TRANSPLANTATION AGAINST DONOR-SPECIFIC CYTOTOXIC T-WARM ANTIBODIES (CYCLOSPORIN ERA)[a]

	No.	Survival (months)				
		>1	>2	>6	>12	Now
Negative cross-match	31	24 (77%)	22	14	3	21 (68%)
Positive cross-match	8	5 (63%)	5 (63%)	2	1	4 (50%)
Cross-match not done	14	13 (93%)	10	2		12 (86%)

[a] Data from 53 consecutive primary transplants at the University of Pittsburgh.

rejection (45). In two of our Pittsburgh cases, two incompatible donors were used (Table 4). The course of one of these patients is shown in Figure 6. We have tried to avoid this practice since blood group compatible donors can usually be found.

TABLE 4. CASES OF DONOR-RECIPIENT BLOOD GROUP INCOMPATIBILITY IN 53 CONSECUTIVE PRIMARY LIVER TRANSPLANTATIONS AT THE UNIVERSITY OF PITTSBURGH

OT	Incompatibility	Early graft function	Outcome
193	A → B	Good	Well, 12 months
196	A → B	Good	Died, systemic aspergillosis, 8 days

IMMUNOSUPPRESSION FOR HUMANS (THE KIDNEY TRANSPLANT PROTOTYPE)

It was important to demonstrate in animals that chronic survival is possible after liver transplantation under immunosuppression. However, such laboratory investigations contributed relatively little to the immunosuppressive regimens which have been used clinically. Liver transplantation, either in animals or man, was too complex to be used as a model to evaluate drugs or drug combinations. Instead, all methods to prevent or reverse rejection of whole organs have depended upon observations after renal transplantation.

The immunosuppressive protocols that have been developed for human renal transplantation are summarized in Table 5, exclusive of the historically important trials with total body irradiation (68). Because the first genuinely promising drug, azathioprine (8), proved to be effective only rarely when given alone (69), the "modern" era was not entered until it was realized that azathioprine and prednisone have an additive (or possibly synergistic) effect (67, 70–73). At the outset, our policy was to begin therapy after renal transplantation with azathioprine and to add high doses of prednisone with the first signs of rejection (70). Because it was rare to escape rejection even after transplantation from closely related donors, our recommendation (67) was to begin treatment with both drugs immediately after transplantation with a gradual reduction in prednisone. Such "double-drug therapy" has been the most commonly used immunosuppression for almost 20 years.

With transplantation from consanguineous donors under double-drug treatment, chronic renal graft function was achieved almost immediately in more than two-thirds of cases. However, during the first year after *cadaveric* renal transplantation, the graft loss rate in multicenter compilations remains at about 50% (74, 75). Liver recipients for whom cadaveric donors were obligatory, and who did not have the option of fall-back maintenance on an artificial organ therapy analogous to renal dialysis in the event of rejection, were confronted with a bleak outlook.

Between 1963 and 1979, several alternative therapeutic programs were introduced for renal transplantation (Table 5); all were modifications of or additions to the original double-drug therapy. A promising approach involved lymphoid depletion with ALG (36) which was given i.m. or i.v. as an adjunct to azathioprine and prednisone during the first few weeks or months when the risk of rejection is the greatest. "Triple-drug therapy" has been the second most commonly used technique of immunosuppression. A conceptually important but pragmatically inconsequential detail was that cyclophosphamide could be freely substituted for azathioprine (76). The results of 1-year graft survival after cadaveric renal transplantation under triple-drug therapy were improved in most centers. After the discontinuance of ALG, there was an unacceptable rate of delayed rejection which, not surprisingly, also occurred after liver transplantation (32). The alternative of temporary lymphoid depletion with thoracic duct drainage (TDD) (77) in preparation of patients for cadaveric renal transplantation (78) had the same disadvantage (79). Efforts to use preoperative TDD in liver recipients usually created insurmountable problems because of the prodigious quantities (as much as 2 liters per hr) of thoracic duct lymph which patients with hepatic insufficiency produced (80). Lymphoid depletion by total lymphoid irradiation for conditioning before grafting (81, 82) has not been tried in liver recipients.

There was widespread discontent with all techniques of immunosuppression from 1963 to 1978. Many kidney transplant surgeons attempted to escape the consequences of this therapeutic *cul de sac* by exploiting developments in tissue typing and matching, or by systematically conditioning prospective renal recipients with preoperative blood transfusions. The former efforts yielded disappointing results after cadaveric kidney transplantation; the latter practice of conditioning by transfusion allowed an increased success rate in patients not accidentally sensitized during their preparation. In any event, liver transplantation candidates usually were too ill to wait for a well-matched liver or to undergo stages of preoperative preparation. For future trials of liver transplantation, it was necessary to hope for better immunosuppressive drugs. This did not seem realistic until the advent of cyclosporin A.

Cyclosporin A is an extract from the fungi *Cylindrocarpon lucidum* and *Trichoderma polysporum*. It was discovered and characterized biochemically by scientists at the Sandoz Corp., Basel, Switzerland. Cyclosporin A was shown to be immunosuppressive by Borel et al. (83, 84) in mice, rats, and guinea pigs. The drug depressed humoral and cellular immunity with a preferential and quickly reversible action against T-lymphocytes. These effects were not accompanied by bone marrow depression which frequently limits the doses of azathioprine and cyclophosphamide. The unusual effectiveness of cyclosporin A in preventing or delaying rejection of mouse skin homografts was demonstrated by Borel et al. (83,

TABLE 5. CLINICAL IMMUNOSUPPRESSIVE DRUG REGIMENS DEVELOPED WITH KIDNEY TRANSPLANTATION

Agents	Year described and reported	Place	Deficiencies	Used for liver transplantation
Azathioprine	1962 (69)	Boston	Ineffective, dangerous	No
Azathioprine—Steroids	1963 (70–73)	Denver, Boston, Richmond, Edinborough	Suboptimal	Yes
Thoracic duct drainage as adjunct	1963 (77)[a]	Stockholm	Nuisance; requires 20–30 days pretreatment	Yes
ALG as adjunct	1966 (36)	Denver	Still suboptimal	Yes
Cyclophosphamide substitute for azathioprine	1970 (76)	Denver	No advantage except for patients with azathioprine toxicity	Yes
Total lymphoid irradiation	1979 (81, 82)	Palo Alto, Minneapolis	Dangerous; extensive preparation; not quickly reversible	No
Cyclosporin A alone	1978–1979 (90, 91)	Cambridge	Suboptimal	Yes
Cyclosporin A—Steroids	1980 (92, 93)	Denver	Under evaluation	Yes

[a] It was not realized until much later that pretreatment for 3 to 4 weeks before transplantation was a necessary condition (78).

84). Analogous observations in which heart, kidney, liver, and pancreatic grafts were protected in rats, rabbits, dogs, and pigs were reported by Kostakis (85), Calne (86–88), and Green (89) and their associates.

When cyclosporin A was first used in patients by Calne and coworkers (90, 91), it was hoped that no other drug would be routinely required. Our dissenting opinion is that cyclosporin A should be combined with steroid therapy from the outset (92, 93). The extent to which steroids are required with cyclosporin A remains to be clarified, but it is clear that kidney survival of greater than 80% can be expected 1 year after primary cadaveric transplantation (93, 94). Long-term follow-up of our original recipients and those of Calne has not shown a tendency for patients under cyclosporin A to have "catch-up" graft losses or unexpected delayed morbidity from other causes. We and Calne have not had the disillusionment reported by Carpenter et al. (95) and Sweny et al. (96) in their first trials with cyclosporin A for cadaveric renal transplantation.

As new teams begin using cyclosporin A, it will be important to avoid unrealistic expectations about early convalescence that could be engendered by the high success rates achieved after cadaveric renal transplantations. In a recent analysis of 42 consecutive cadaveric renal recipients (97), only one-third had a completely uneventful recovery. Of the remainder, most developed rejection which was usually reversed with augmented steroid therapy. In every case, the major differential diagnosis was rejection *vs.* nephrotoxicity from cyclosporin A.

Nephrotoxicity of cyclosporin A was first noted by Calne (90, 91) and Powles (98), and has been confirmed elsewhere (92, 99). To sharpen the interrelationship between therapeutic effect and toxicity, pharmacologic (cyclosporin A blood and/or plasma levels) and immunologic monitoring were advocated by Keown (100), Rynasiewicz (101), and Kahan (102). Our techniques of management have not depended upon these monitoring techniques. Fortunately, nephrotoxicity usually has promptly reversed with reduction of cyclosporin A doses. As a last resort, a change from cyclosporin A to azathioprine has been made but at an increased risk of rejection (99).

Most other side effects of cyclosporin A (90–94) are not serious and include gingival hyperplasia, tremor, regional flushing or vague abdominal discomfort just after drug ingestion, and development of breast fibroadenomas in women. Although hepatotoxicity occurs in about one-fifth of cases (103), it is rarely serious enough to necessitate a change to azathioprine.

The most publicized question about cyclosporin A concerns its potential oncogenicity. It has been known for 15 years that conventional immunosuppression results in an increased incidence of *de novo tumors*, of which approximately one-third are lymphomas (104). Early reports by Calne (91) of lymphoma development in patients treated with cyclosporin A were not surprising, although the incidence of three lymphomas in 34 recipients was sobering. Calne attributed this high incidence to the concomitant use of other cytotoxic drugs and possibly steroids. In our own experience with cyclosporin A and steroid therapy in almost 200 cadaveric renal recipients, there have been two lymphomas. One was an incidental finding at autopsy following a fatal infection (93). The other was successfully treated by intestinal resection after it had caused a perforation (97). To our knowledge, no *de novo* epithelial tumors have been seen in renal recipients. As experience with cyclosporin A accumulated worldwide, the spectre of this drug being a spectacular tumor producer has receded. None of the liver recipients treated with cyclosporin A and steroids has developed new malignancies.

IMMUNOSUPPRESSION AND LIVER TRANSPLANTATION

Two patients are known to have been given orthotopic liver grafts without immunosuppression or with steroid therapy only. The first patient was in the Cambridge series (7); the other was treated in Oslo (21). One factor in these decisions may have been the demonstration in dogs (32, 33) and pigs (32, 40–42) that rejection of liver grafts was less severe than that after renal transplantation. In addition, the English recipient had hepatitis which it was feared would be reactivated by immunosuppression. Both organs promptly failed with early death of the patients.

All other patients were given some variant of the double- or triple-drug treatment summarized in Table 5. Our first five recipients and occasional ones later were treated with azathioprine and prednisone. The same treatment was used for almost all patients in the Cambridge series from 1968 through 1979.

Triple-drug treatment was used in the majority of recipients from 1966 through 1979. The most common regimen was azathioprine, prednisone, and a variable course of i.m. ALG which was begun on the day of operation. The duration of ALG was usually limited to a few weeks because of sensitization of the recipients to horse, rabbit, or goat globulin; however, treatment with ALG was continued in some cases for 6 to 12 months.

In a modification of triple-drug therapy (Table 5), cyclophosphamide instead of azathioprine was given to 16 patients (OT 42–57) from March, 1971 to August, 1972 (105). Six (37.5%) recipients lived for at least 1 year, and four (OT 42, 46, 53, 56) are still alive more than 10 years later. From a few months to several years after transplantation, all surviving patients were switched to azathioprine. Because the results during this period were not markedly different than with the original triple-drug management, cyclophosphamide was not further used as a first line drug.

In 1978 and 1979, TDD was used as an adjunct to therapy with azathioprine and prednisone in 21 patients (80). TDD was started 10 to 18 days before transplantation in 2 patients, on the day of operation in 17 patients, and 2 and 4 weeks after transplantation in the other two. Six (31.6%) of 19 recipients who had TDD started prior to or on the day of transplantation lived for at least 1 year and five are alive after 3⅔ to 4⅓ years. The management dilemma was that in the kidney transplantation model, TDD was ineffective unless applied at least 3 weeks in advance of transplantation (78), but potential liver recipients could not tolerate the chronic, high-volume thoracic lymph drainage associated with hepatic disease. If TDD is to be tried again in liver transplantation, a closed system will be required in which lymphocytes can be removed in transit without the necessity for lymph removal and later reinfusion.

Calne et al. (91) were the first to use cyclosporin A for liver transplantation. In their first two cases, cyclosporin was used alone. However, most of their experience has been with delayed administration of the drug (53, 106). Azathioprine (1.5 mg per kg per day) and prednisolone (0.4 mg per kg per day) were used until renal and hepatic functions were adequate. Then, cyclosporin A (10 mg per kg per day) was begun, and the steroid dose was slowly reduced to zero. The supervention of acute rejection during treatment with azathioprine and prednisone was troublesome and, in the last review by Calne et al. (53), they recommend shortening this period.

Our practice (107–109) has been to start cyclosporin A a few hours preoperatively with an p.o. dose of 17.5 mg per kg (Figures 5 to 7). Cyclosporin A is continued daily, but with reduced i.m. or i.v. quantities (Figure 7) until p.o. diet is resumed. Subsequently an p.o. dose of 17.5 mg per kg per day is given, usually with half the daily dose every 12 hr. The quantities are reduced subsequently if toxic manifestations develop, of which nephrotoxicity has been the most important (Figures 5 and 6). Usually, steroids are also started on the day of operation. For adult patients who leave the operating room in relatively good condition, a 5-day burst of prednisolone is given, starting at 200 mg and stopping with a maintenance dose of 20 mg per day (Figure 5). Further reductions of cyclosporin A and steroid doses are made on an individualized basis. Initial and maintenance therapy with steroids are reduced in infants and children (Figure 6).

If the patient was in poor postoperative condition, the initial burst of high-dose steroid therapy was omitted for a few days or greatly reduced (Figure 7). A few patients suspected of having nephrotoxicity from cyclosporin A were switched temporarily to azathioprine with resumption of cyclosporin A treatment as renal function improved (Figure 6). With less severe renal impairment (Figures 5 and 7), the dose of cyclosporin A was reduced. No patient has been changed to azathioprine permanently. If rejection occurred in spite of this therapy, the principal responses have been to administer intermittently large i.v. doses of hydrocortisone (or prednisolone) (Figures 5 and 7), repeat the original 5-day burst of steroids (Figure 7), and settle at a higher maintenance level of steroids. Although cyclosporin A does not permit much dose maneuverability, it has sometimes been possible to increase the amounts given despite the risk of nephrotoxicity.

REJECTION AND ITS MODIFICATION

To interpret much of the statistical information to be presented later in this review, it will be necessary to describe the features of homograft rejection as these have been perceived by the pathologist and surgeon.

THE MORPHOLOGIC EVENTS OF REJECTION

Despite treatment with any of the immunosuppressive regimens so far used, rejection of human hepatic homografts has been observed. A clear picture can be pieced together from studies of orthotopic liver transplantation in rats, dogs, pigs, baboons, and humans of the sequence of pathologic events which occur when a modified or unmodified recipient rejects a liver graft (110–113).

In untreated members of all species (the principal observations have been in dogs), there is a quiescent phase of at least 2 or 3 days during which only rare small lymphocytes are found in the tissue spaces of the liver

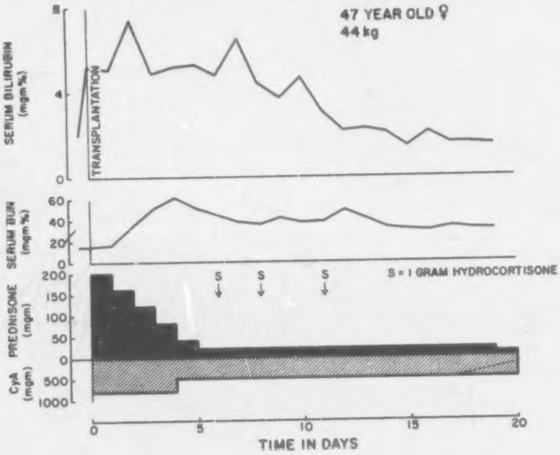

FIG. 5. Double-drug immunosuppression with cyclosporin A and steroids. The patient (OT 198) had a hepatoma, α-1-antitrypsin deficiency, and chronic active hepatitis. The reduction of the cyclosporin A dosage after 4 days was because of the increasing azotemia. The boluses of hydrocortisone were given because of a possibly unwarranted suspicion of early rejection.

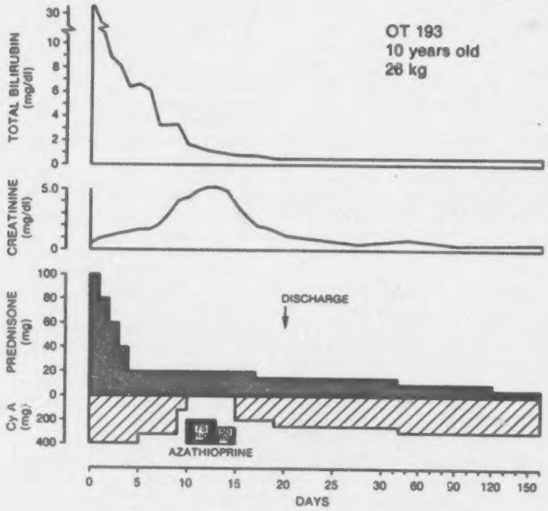

FIG. 6. Immunosuppression with cyclosporin A and steroids (plus temporary azathioprine) in a 10-year-old girl (OT 193). Note that the 5-day opening burst of prednisone therapy was scaled down because of her small size. The temporary discontinuance of cyclosporin A and replacement with azathioprine between postoperative Days 10 and 15 was because of probable cyclosporin nephrotoxicity. The patient who was of B blood type was given the liver of an A donor.

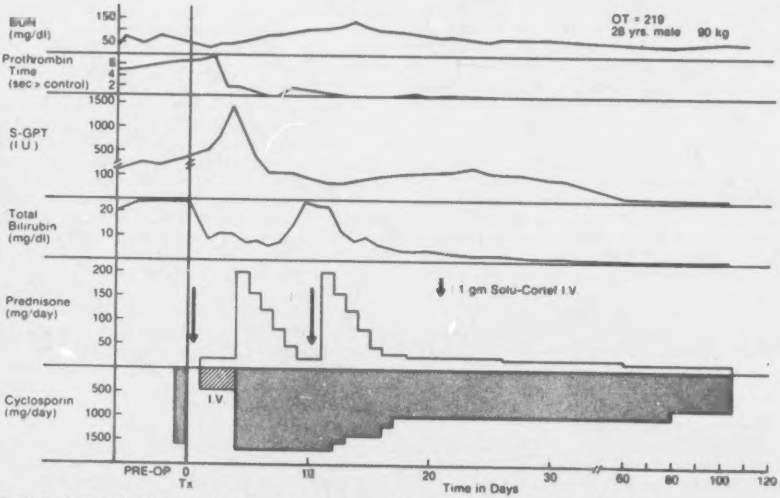

FIG. 7. Deviation from standard steroid therapy in a patient (OT 219) whose perioperative condition was frail. The 5-day burst of postoperative steroids was begun several days postoperatively but had to be repeated when rejection supervened. Before operation, the patient had hepatorenal syndrome and encephalopathy and he had been on a ventilator for more than 1 week. Because of defective clotting, efforts to place central venous lines before starting transplantation resulted in uncontrolled hemorrhage with the loss of 20 liters of blood. The subclavian and innominant vessels were explored through cervical and thoracotomy incisions, and the bleeding was mechanically controlled before transplantation was started. The blood loss from placement of the vascular lines exceeded that incurred during transplantation. The patient survived because of prompt correction of the coagulation abnormalities. He is at home 5 months after transplantation.

which remain normal except for nonspecific changes. However, during this period, large pyroninophilic cells start proliferating in the paracortical zones of the host lymph nodes. About 3 days after transplantation, lymphoid cells begin to leave portal vein tributaries randomly throughout the graft. The venous endothelium is separated from the basement membrane, and fibrin collects in the subendothelial space. After passing through the vessel wall, lymphocytes accumulate in the portal tracts. Smaller numbers of lymphoid cells migrate through the walls of the central vein and the endothelial lining of sinusoids. These cells invade the space of Disse and some enter between hepatocytes. Immunoglobulins are rare in the cytoplasm of the infiltrating cells at this time.

Associated with cellular infiltration, the cells of many sinusoids disintegrate, blood flow through the liver begins to decrease, and some centrilobular cells die. As the centrilobular necrosis progresses to midzonal necrosis, liver function becomes affected. Inspissated bile appears in surviving bile canaliculi and lipid droplets accumulate in the hepatocytes around the portal tract. Shortly before the death of the untreated recipient, foci of fibrinoid necrosis sometimes occur in the walls of small branches of the hepatic artery associated with deposition of immunoglobulin and complement in the intima and media.

When rejection is mild, as in pigs (115), or is modified by immunosuppressive agents, as in dogs and humans (110, 112-114, 116), destruction of hepatocytes ceases, cellular infiltration diminishes and may disappear, but the central part of the lobular reticulin framework often collapses. Accumulation of bile in surviving centrilobular hepatocytes and in bile canaliculi occurs; the cause of this severe cholestasis is not known and may be secondary to widespread loss or distortion of canalicular microvilli. An alternative possibility has been put forward by Myburgh et al. (111) who drew attention to the progressive hypertrophy and dilatation of smooth endoplasmic reticulum in the centrilobular hepatocytes and suggested that these intracellular changes might be caused by humoral antibody and result in disrupted cholesterol and bile salt metabolism with production of excess lithocholate. In some patients, the larger interlobular bile ducts disappear as modified rejection continues. This phenomenon is characterized by rapid and relentless rise in serum bilirubin (49-51, 116).

As rejection progresses, connecting bands of reticulin are often laid down between the central areas, subdividing the lobules. What triggers progression to hepatic fibrosis in some grafts is unknown; excess lithocholate has been implicated (111). In some patients, cirrhosis is produced. Another characteristic feature of chronic rejection is progressive thickening of the intima of the branches of the hepatic artery in the homograft. The intima contains fat-laden smooth muscle cells and macrophages, and the lumen is narrowed or occluded. These arterial changes occur in many long-surviving liver homografts. The accumulation of immunoglobulins and complement in the altered vessel wall has raised the possibility that this damage is a late manifestation of rejection brought about by circulating antibody. Deposition of immunoglobulins is less striking in hepatic grafts than in transplant kidneys (117), prompting speculation that hepatic rejection was more a phenomenon of cell-mediated immunity (as opposed to damage by circulating antibodies) than has been thought to be the case with rejecting kidney grafts.

Some histopathologic changes in liver homografts may be caused by hepatotoxic drugs, viral hepatitis, or other factors. However, a comparison of changes in human specimens with those in animal homografts emphasizes that the major alterations are immunologic in etiology.

THE CLINICAL MANIFESTATIONS OF ACUTE REJECTION

Rejection as defined by us (32) and Williams and Calne (7) in patients treated with conventional immunosuppression also occurs during treatment with cyclosporin A and steroids. Many patients lose their appetites and become depressed. Fever, vague upper abdominal pain, and ascites are variable. By palpation, grafts are frequently swollen, hard, and mildly tender. Radioisotopes used for liver scanning are poorly concentrated, whether these depend upon parenchymal or reticuloendothelial function. Elevations may occur in serum bilirubin, alkaline phosphatase, and transaminases. Failure of synthetic function is most readily detected by measurements of prothrombin time.

The various manifestations of rejection occur in different combinations, to variable degrees, and at unpredictable times. The resulting patterns have been categorized as "anicteric," "indolent," and "crisis" (32). With a rejection crisis, jaundice can develop with astonishing rapidity, usually just after or accompanied by major rises in transaminases. The insidious indolent rejections have been the most difficult to reverse.

All patterns of graft deterioration are nonspecific. Proven alternative etiologies include ischemic injury, biliary obstruction, cholangitis, hepatitis (B virus, cytomegalovirus, adenovirus, herpes), and drug toxicity. Consequently, diagnostic procedures, often including cholangiography and needle biopsy, must be considered if the postoperative evolution is not satisfactory. In the interim, steroid dosage is temporarily increased and returned to baseline if a diagnosis other than rejection is established. Clinical management is particularly difficult and fraught with error if good initial graft function was not achieved.

A devastating complication of rejection, termed "septic hepatic gangrene," occurred in patients who were treated with azathioprine, ALG, and relatively low doses of prednisone. After days or weeks of slightly abnormal hepatic function, these patients developed massive hepatic necrosis with extremely elevated serum transaminase activities and deterioration of other measures of hepatic function. Raging fevers, bacteremia, and disappearance on liver scans of large portions of hepatic parenchyma signaled regional infarctions within the transplants. Kinking of lobar or segmental hepatic arteries was originally postulated to be responsible for this complication (5), but the most important factor is poorly controlled rejection (32). With diminution in total hepatic blood flow, as was documented in canine experiments by Groth et al. (31), invasion of the ischemic homograft by microorganisms from the adjacent intestinal tract is not surprising.

Study of patients with septic hepatic gangrene and confirmatory observations by Brettschneider et al. (118) after canine and porcine liver transplantations clarified the interaction between rejection and homograft bacterial colonization. In animal studies, the normally low incidence of positive cultures from liver tissue of dogs and pigs increased after sham operations. When an hepatic ischemic injury was added by performance of simulated autotransplantation, all livers became contaminated, primarily with the same organisms concomitantly present in the upper intestine. Bacterial counts were somewhat lower if the common bile duct was left intact than when the duct was ligated and bile drainage restored by cholecystoenterostomy. The bacterial changes were more pronounced in liver homografts transplanted to unmodified or immunosuppressed animal recipients.

Presumably, any ischemic or necrotic area can become a septic focus, particularly if the host is given immunosuppressive therapy and cannot respond normally to invading microorganisms. The spectrum of resulting infections under conventional immunosuppression has been well studied (32, 119–121). Paradoxically, one of the most important ways to prevent nontreatable liver infection is to protect the graft with potent immunosuppression, especially during the early postoperative period. The second obvious step is to provide systematically designed antibiotic therapy intraoperatively and for several days thereafter.

Acute cellular rejection in grafts sampled by biopsy or at autopsy has been encountered many months or years after transplantation. Some patients were known to have discontinued their medications but others had been given unwise advice about lowering maintenance medications. Increased steroid therapy was given under such circumstances.

Chronic Rejection

The diagnosis of chronic rejection was restricted to patients whose grafts had arterial intimal thickening, hepatic fibrosis, and other findings described previously. These findings are not necessarily time-related since they often develop within the first few months. Clinical manifestations of chronic rejection were not much different from those of chronic liver failure from endstage disease of differing etiologies. Treatment with increased immunosuppression was ineffective.

SURVIVAL AFTER TRANSPLANTATION

The introduction of cyclosporin A and steroids has had such a major influence upon results that patients have been divided into those treated before and after this event. By so doing, it is possible to reexamine several factors whose significance was previously unclear.

Precyclosporin Era (1963 to 1979)

Between 1963 and the end of 1979, 170 patients had liver replacement. In previous publications, the identification of individual recipients by orthotopic transplantation (OT) numbers made it possible for the interested reader to follow their progress from report to report. The same code numbers will be used throughout this review.

In past reports (45, 80, 107), the first 170 recipients were divided into the three successive series summarized in Table 6 and Figure 8. In the first, second, and third of these consecutive groups, 1-year survival was 28.8, 50, and 34.5%.

Of the 56 recipients who survived the first postoperative year, 23 died at the times shown in Table 6. Although 13 of 23 late deaths were in the second postoperative year, deaths occurred as late as 6 years. Of the original 170 patients, 33 (19.4%) are alive after follow-ups of 2½ to 12½ years. Twenty have survived for more than 5 years and four are into the second postoperative decade.

There was an almost equal division in the total period of 1963 to 1979 between adult (≥19 years) and pediatric (≤18 years) recipients. From the sixth month onward, the younger patients had about a 10% survival advantage (Figure 9).

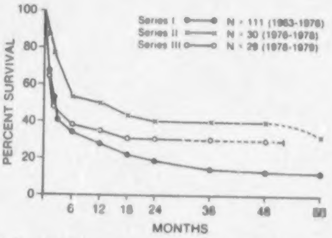

Fig. 8. Survival of three consecutive series of patients treated with orthotopic liver transplantation under conventional immunosuppression. The *dashed lines* in Series 2 and 3 are actuarial projections.

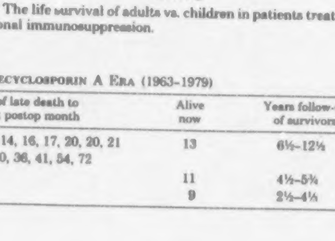

Fig. 9. The life survival of adults vs. children in patients treated with conventional immunosuppression.

Table 6. Late Deaths in 170 Patients During Precyclosporin A Era (1963–1979)

	No.	Alive after 1 year	Died after 1 year	Time of late death to nearest postop month	Alive now	Years follow-up of survivors
Series 1	111	31 (28.8%)	18	12, 13, 13, 13, 14, 16, 17, 20, 20, 21 25, 26, 28, 30, 36, 41, 54, 72	13	6½–12½
Series 2	30	15 (50%)	4	17, 23, 49, 56	11	4½–5¾
Series 3	29	10 (34.5%)	1	13	9	2½–4⅓

Table 7 summarizes the results in the Cambridge-King's College trials from 1968 through early 1980 (53, 122). In this series, 22 (23.7%) of the first 93 recipients lived for at least 1 year, with 11 subsequent deaths during the second to sixth years; the 11 survivors had been followed for 1 to 6 years. The better 1-year survival in the American compared to the English trial (33 *vs.* 24%) was partly illusory since Calne and Williams accepted for surgery few pediatric patients with whom (Figure 9) our best results were obtained in those years.

Our results in the pediatric age group after transplantation for different indications are given in Table 8. Similar information for adult recipients is provided in Table 9.

CYCLOSPORIN ERA (1980 TO 1982)

The longest follow-ups for our patients treated with cyclosporin A and steroids are only 2½ years. During the first 9 months of 1980, 14 patients entered into this trial at the University of Colorado (108); 2 died during the operation, and 1 died after 19 days. The other 11 patients survived for more than 1 year. Eight are alive after 21 to 28 months. The 1-year survival of 78.6% could have represented a sampling accident. However, at the University Health Center of Pittsburgh, 26 patients were treated in 1981. Five died in the first postoperative month, and additional deaths occurred in the second, third, and fourth months. With follow-ups of 6 months to more than 1 year, the remaining 18 (69.2%) recipients are alive and at home; none has poor hepatic function.

TABLE 7. ACTUAL 1-YEAR SURVIVAL[a] IN CAMBRIDGE/KING'S COLLEGE SERIES OF 93 CASES (1968 TO FEBRUARY, 1980)

No.	1 week	6 months	1 year
93	77 (82.8%)	31 (33.3%)	22 (23.7%)

[a] Information from (122). Of the 22 one-year survivors, 11 had subsequently died from 1 to more than 5 years postoperatively. The other 11 were living in their second to sixth postoperative year. An actuarial projection of this data beyond 1 year is depicted in Figure 10.

TABLE 8. INDICATIONS FOR TRANSPLANTATION AND SURVIVAL IN PEDIATRIC PATIENTS (≤18 YEARS) FROM 1963 THROUGH 1979 (PRECYCLOSPORIN A)

	No.	Survival (months)				
		>1	>2	>6	>12	Now[a]
Biliary atresia	51	37 (73%)	27 (53%)	16 (31%)	14 (27%)	7 (14%)
Inborn metabolic errors	13[b]	12 (92%)	11 (85%)	8 (62%)	8 (62%)	6 (46%)
Chronic aggressive hepatitis	13	11 (85%)	10 (77%)	7 (54%)	5 (38%)	3 (23%)
Hepatoma	3[c]	3	3	2	2	0
Neonatal hepatitis	2	1	1	1	1	0
Congenital hepatic fibrosis	2	1	1	1	1	1
Secondary biliary cirrhosis	2[d]	2	2	2	2	1
	86	67 (78%)	55 (64%)	37 (43%)	33 (38%)	18 (21%)

[a] Follow-ups for living patients are 2½ to 12½ years.

[b] Inborn errors

α-1-antitrypsin deficiency	9
Wilson's disease	2
Tyrosinemia	1
Type IV glycogen storage disease	1
	13

[c] Five other patients had incidental malignancies (4 hepatomas and 1 hepatoblastoma) in their excised livers. The principal diagnoses in these five cases were biliary atresia (3 examples), α-1-antitrypsin deficiency (1 example), and congenital tyrosinemia (1 example). The diagnosis of the neoplastic change was known in advance only in 2 of the 5 cases.

[d] Secondary to trauma or choledochal cyst (one each).

TABLE 9. INDICATIONS FOR TRANSPLANTATION AND SURVIVAL IN ADULT PATIENTS (≥19 YEARS) FROM 1963 THROUGH 1979 (PRECYCLOSPORIN A)

	No.	Survival (months)				
		>1	>2	>6	>12	Now[a]
Chronic aggressive hepatitis	33	21 (64%)	17 (52%)	14 (42%)	11 (33%)	7 (21%)
Alcoholic cirrhosis	15	8 (53%)	5 (33%)	4 (27%)	4 (27%)	3 (20%)
Primary malignancy	15[b]	9 (60%)	7 (47%)	4 (27%)	3 (20%)	1 (7%)
Sclerosing cholangitis	7	7	4	2	2	0
Primary biliary cirrhosis	6	3	3	2	1	1
α-1-antitrypsin deficiency	2	1	1	0	0	0
Secondary biliary cirrhosis	2[c]	1	1	1	1	1
Hemochromatosis	1	1	0	0	0	0
Protoporphyria	1	0	0	0	0	0
Budd-Chiari syndrome	1	1	1	1	1	1
Acute hepatitis B	1	1	1	0	0	0
	84	53 (63%)	40 (48%)	28 (33%)	23 (27%)	14 (17%)

[a] Follow-ups for living patients are 2½ to 8½ years.

[b] Seven hepatomas, 5 duct cell carcinomas (Klatskin), 1 cholangiocarcinoma, 1 hemangioendothelialsarcoma, and 1 unclassified sarcoma.

[c] One example each of possible duct hypoplasia and choledochal cyst; both patients had had multiple operations.

The pattern of predominantly early mortality seen in 1980 and 1981 has continued into 1982. Of the first 27 recipients treated in 1982, 8 died. Six, one, and one of these deaths were in the first, second, and third postoperative months, respectively.

It is too early to assess the rate at which late deaths will occur, since only 18 patients treated with cyclosporin A have reached or passed the 1-year mark. Of these, three died in their thirteenth, sixteenth, and twentieth postoperative months for reasons that will be considered in the next section.

The actuarial survival calculated from the cases in the cyclosporin era studied to date is shown in Figure 10. In comparison to our previous experience in the precyclosporin era and in comparison to the Cambridge-King's College compilation, survival has more than doubled.

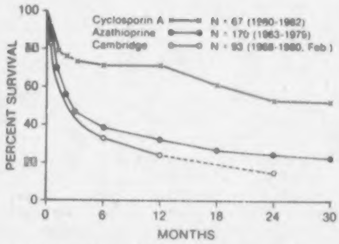

FIG. 10. The actuarial survival of patients treated with cyclosporin A and low-dose steroids compared to the actual 1-year survival obtained under conventional immunosuppression by us (azathioprine) and the workers at Cambridge. The data for the Cambridge curve were obtained from published reports (53, 122).

The results calculated for the first 12 postoperative months have not been different in adults and children (Figure 11). A breakdown of results according to original disease in the pediatric and adult cases is provided in Tables 10 and 11.

The influence of cyclosporin A upon survival in the Cambridge-King's College trials has not been clearly defined, because the drug has not been regularly used and because it was started late in most cases after an initial course of azathioprine and steroids. Nevertheless, improved results have been attributed by Calne et al. (53) to better immunosuppression.

CAUSES OF MORTALITY

PRECYCLOSPORIN ERA

Early Death. The appalling early mortality after liver transplantation has prompted exhaustive clinical-pathologic analyses of our failed cases. Using the OT code numbers of the patients, the results have been reported in such a way that individual assessment of almost every early death in the first 170 cases can be made by the interested reader (43, 45, 80). Mortality figures included the use of grafts damaged by ischemia, massive operative hemorrhage, thrombosis of the reconstituted homograft blood supply, intraoperative cerebral air embolism (44), unsuspected recipient abnormalities (such as prior thrombosis of the portal vein), hopeless anatomical situations created by multiple previous operations, irreversible preexisting debilitation, and (above all) defective biliary tract reconstruction.

With or without such factors, overwhelming infection was frequently a terminal event. At autopsy, histopathologic findings of acute rejection were found in 10 to 15% of cases, prompting speculation that over immunosuppression, especially with prednisone, may have been responsible for unnecessary deaths (43).

When serial biopsies were obtained in later cases (45, 80), this simplistic view had to be revised. Many biopsies contained unmistakable findings of rejection for which the appropriate response had been more steroids. After death caused by infection, the findings of rejection were absent. The conclusion was reached that even after a perfect operation, the unacceptable acute mortality would remain until improved immunosuppression be-

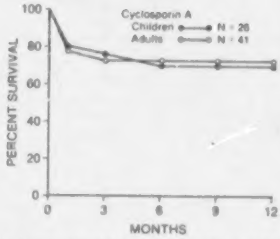

FIG. 11. The 1-year actuarial survival of adults vs. children after liver transplantation under immunosuppression with cyclosporin A and steroids.

TABLE 10. INDICATIONS FOR TRANSPLANTATION IN PEDIATRIC PATIENTS (≤18 YEARS) FROM MID-1980 TO MAY, 1982 (CYCLOSPORIN ERA). FOLLOW-UPS FOR SURVIVORS ARE 1-21 MONTHS

	No.	Living
Biliary atresia[a]	11	8
α-1-antitrypsin deficiency[b]	4	2
Chronic aggressive hepatitis	2	2
Byler's disease[c]	2	1
Secondary biliary cirrhosis[d]	1	0
Budd-Chiari syndrome	1	0
Neonatal hepatitis	1	1
Subacute Wilson's disease[b]	1	1
Tyrosinemia[b]	1	1
Type I glycogen storage disease[b]	1	1
Sea-blue histiocyte syndrome[b]	1	1
	26	18 (70%)

[a] Two had Alagille's syndrome.

[b] Inborn errors of metabolism. The children with tyrosinemia and sea-blue histiocyte syndrome had incidental hepatomas in their cirrhotic livers.

[c] Diagnosis equivocal in one case.

[d] Choledochal cyst with multiple operations.

TABLE 11. INDICATIONS FOR TRANSPLANTATION IN ADULT PATIENTS (≥19 YEARS) FROM MARCH 1, 1980 TO MAY 1, 1982 (CYCLOSPORIN ERA). FOLLOW-UP FOR SURVIVORS WAS 1-27 MONTHS

	No.	Living
Chronic aggressive hepatitis	14	9
Malignancy[a]	9	7
Primary biliary cirrhosis	6	5
Secondary biliary cirrhosis	4	2
2 trauma		
1 Caroli		
1 choledochal cyst		
Sclerosing cholangitis	3	2
α-1-antitrypsin deficiency	2	1
Budd-Chiari syndrome	2	1
Adenomatosis[a]	1	1
	41	28 (68%)

[a] One patient in each group had previous (1 and 4½ years earlier) right hepatic trisegmentectomy. At transplantation, the regenerated left-lateral segment was replaced with a whole liver.

came available. Both nonimmunologic and immunologic complications have continued to cause early deaths in the cyclosporin era albeit at a reduced rate.

Deaths After 1 Year. Assessment of the reasons for late death in older cases may help to predict the spectrum of problems which can be expected in future patients. The causes of mortality after 1 year in patients treated with conventional immunosuppression are listed in Table 12. Recurrent liver failure was responsible for death in ¾ of 23 patients, if the four who died after attempted retransplantation are included. In three patients, the main mortality factor was recurrence of malignancy. One of the late deaths was caused by chicken pox hepatitis during an epidemic on the transplantation ward. The patient (OT 112) whose death was classified under self-abuse was an alcoholic, drug abuser, and derelict who resumed the same life style after transplantation. Fifty-six months after transplantation, he was found unconscious in a ditch in Florida and died of pneumonitis.

The dominant pathologic diagnoses of the 24 first or second grafts which functioned chronically in these 23 patients are listed in Table 13. Chronic rejection was the most common final diagnosis, followed by biliary obstruction and recurrent cancer. There were two examples each of chronic hepatitis and portal vein thrombosis.

These findings differ from those reported by Calne et al. (53) in 11 patients who died after 1 year; recurrent carcinoma was the main homograft abnormality in five patients. In the other six grafts, there was biliary sludge and cholangitis. Chronic rejection was not mentioned. Our findings suggest that ongoing problems with immunologic control will continue to take a gradual toll long after successful transplantation, whereas interpretation of the pathologic findings in the English recipients is different. Clarification of this divergence of observations will be important.

TABLE 12. CAUSES OF 23 DEATHS[a] AFTER 1 YEAR OF PATIENTS TREATED WITH AZATHIOPRINE (OR CYCLOPHOSPHAMIDE), PREDNISONE, AND ALG

Cause of death	No.
Predominant liver failure	8
Liver failure plus sepsis	5
Early after retransplantation	4[b]
Recurrent cancer	3
Predominant sepsis	2
Self-abuse	1
Total	23

[a] Deaths were usually caused by multiple problems, but only the single most important factors are listed.

[b] Infection invariably contributed to death after retransplantation. In addition, two patients had lethal technical complications and two more had rejection.

TABLE 13. PRINCIPAL PATHOLOGIC CHANGES IN 24 LIVER GRAFTS THAT HAD FUNCTIONED UNDER CONVENTIONAL IMMUNOSUPPRESSION FOR 339 TO 2,190 DAYS BEFORE THE DEATH OF THE PATIENT.[a] IN 5 OF THE 24 GRAFTS, TWO DIAGNOSES WERE GIVEN

Pathologic changes	No.
Chronic rejection	11
Biliary obstruction	6
Recurrent cancer	4
Chronic hepatitis	2
Portal vein thrombosis	2
Chronic cholangitis	1
Chicken pox, hepatitis with necrosis	1
Early alcoholic hepatitis	1
Diffuse fatty changes with centrilobular necrosis	1
Total	29

[a] These 24 grafts were from the 23 patients who died after 1 year (Table 12). Seven of the 23 patients were given two livers, but chronic function (682 plus 403 days) was obtained from both organs in only one case (OT 103); in the other six, the pathologic changes are tabulated only for the long-surviving grafts. Most of the specimens were obtained at autopsy, but a few were from surgical or closed biopsies.

CYCLOSPORIN ERA

Twenty-two of the 67 patients treated in 1980 to 1982 died. Three deaths were after 1 year, and the other 19 were early.

Early Death. Fourteen of 19 early deaths, including two on the operating table, occurred in the first postoperative month. In the second, third, and fourth postoperative months, there were 1, 1, and 2 more death(s), respectively (Table 14).

Eight deaths were directly attributable to preexisting anatomic conditions including multiple previous operations (OT 178), earlier portacaval shunt (OT 180), and right-to-left pulmonary shunts secondary to the liver disease (systemic arterial pO_2 was 30 mm Hg) which did not subsequently close (OT 203). However, the most important abnormalities were in liver blood supply or the vena cava (OT 217, 220, 228, 232, 233) which had not been diagnosed preoperatively. At operation, it was not possible to vascularize adequately homografts in 4 of these latter 5 recipients. In the fourth (OT 233), the superior vena cava was discovered at autopsy to have been replaced by two innominate veins which descended into the abdomen and emptied into the inferior vena cava below the renal veins. During the vena caval cross-clamping of the anhepatic phase of transplantation, the child developed an acute superior vena caval syndrome with irreversible brain injury.

Eight early deaths were technical and thus avoidable, including the use of inadequately preserved grafts (OT 185 to 188), hepatic artery thrombosis (OT 183, 225), and complications of biliary tract reconstruction (OT 201, 208). Problems in preservation were encountered in the first four cases at a new institution.

Deaths After 1 Year. Patients died late (Table 14) of recurrent Budd-Chiari syndrome (OT 174), recurrent duct cell carcinoma (OT 176), and after retransplantation after a primary graft was chronically rejected (OT 181).

THE POSSIBILITY OF RETRANSPLANTATION

In assessing ways of reducing patient mortality, it was obvious almost from the beginning that aggressive attempts at retransplantation offered the only chance of survival for many patients whose first grafts failed either early or late. Such efforts, which have been made in 27 patients (2 of the 27 also were given third grafts) since 1968 (Figure 1), usually have born bitter fruit. The few successes that have been achieved have served as an important stimulus for further trials.

TABLE 14. MAJOR CAUSES OF 22 DEATHS IN CYCLOSPORIN ERA

OT	Age	Sex	Pathology before transplant	Major causes of death	Postoperative month of death
174	20	F	Budd-Chiari syndrome, portacaval shunt	Recurrent Budd-Chiari syndrome, liver failure, sepsis	16
176	35	F	Sclerosing cholangitis, duct cell carcinoma	Recurrent duct cell cancer	13
178	37	M	Secondary biliary cirrhosis, gunshot wound to liver	Operative	1
180	40	M	Sclerosing cholangitis, portacaval shunt	Operative	1
181	16	F	Budd-Chiari syndrome	1st graft: chronic rejection 2nd graft: acute rejection 3rd graft: liver failure, renal failure	20
183	8	F	Byler's disease	Hepatic artery thrombosis	1
185	56	M	Klatskin's tumor	Graft necrosis, sepsis	1
186	17	F	Secondary biliary cirrhosis, Caroli's disease	Graft necrosis, sepsis, bile leakage	1
187	37	F	Chronic aggressive hepatitis, portacaval shunt	Graft necrosis	1
188	46	M	Chronic aggressive hepatitis	Graft necrosis, sepsis	1
196	36	F	Chronic aggressive hepatitis	Systemic aspergillosis	1
201	4	M	α-1-antitrypsin deficiency disease	Hemorrhage during exploration of intrahepatic abscess and mycotic aneurysm	2
203	18	M	α-1-antitrypsin deficiency disease, extensive pulmonary A-V shunt	1st graft: graft hypoxia due to pulmonary A-V shunt 2nd graft: graft hypoxia; rejection 3rd graft: graft hypoxia; cerebral hemorrhage	4
208	42	M	Chronic aggressive hepatitis, α-1-antitrypsin deficiency disease, primary biliary cirrhosis	Hemorrhage from hepatic artery, bile duct fistula	3
215	39	F	Primary biliary cirrhosis	Rejection; sepsis due to duodenal stump leakage after total gastrectomy for stress ulcer hemorrhage	3
216	2	F	Biliary atresia, Kasai operation	Chronic rejection, liver failure, sepsis	4
217	44	M	Chronic aggressive hepatitis, splenectomy, portal vein hypoplasia[a]	Operative	1
220	8	F	Secondary biliary cirrhosis, choledochal cyst, portal vein thrombosis[a]	1st graft: graft necrosis 2nd graft: cerebral hemorrhage	1
225	44	M	α-1-antitrypsin deficiency disease	1st graft: rejection, hepatic artery thrombosis 2nd graft: rejection, sepsis	1
226	3	M	Alagille's syndrome, absent hepatic artery[a], hypoplastic portal vein[a]	Graft necrosis	1
232	6	F	Biliary atresia, Kasai operation, absent inferior vena cava[a], malrotation[a]	Diffuse clotting in graft	1
233	2½	F	Biliary atresia, Kasai operation, absent superior vena cava with innominate drainage into inferior vena cava[a]	Perioperative brain death	1

[a] Anomalies or abnormalities not known before operation.

The attempts at retransplantation in 27 patients are summarized in Table 15. Eighteen of 27 second transplantations were within the first 3 months, 3 were between 3 and 12 months, and 6 were after 12½ to 29 months.

Extended subsequent survival occasionally was achieved with early and later retransplantation. The fate of six patients whose lives were significantly prolonged is summarized in Table 16. Much of life for the first four recipients was a nightmare of morbidity because of the combination of high steroid needs and slowly failing graft function. However, the two patients who had successful retransplantation in the cyclosporin A era, 1 and 3 weeks after primary grafting, have had perfect results and are at home 6 and 12 months later on daily prednisone doses of 5 and 15 mg per day, respectively. In the first patient, the primary graft had developed a huge fungus abscess; in the second patient, the first graft had been rejected.

The performance of retransplantation has sometimes been surprisingly easy. The procedure has been greatly simplified by retaining cuffs from the suprahepatic and infrahepatic vena cava and from the portal vein of the first graft. Usually, it has been necessary to perform the arterial anastomosis proximal to the previous site.

THE INFLUENCE OF ORIGINAL DISEASE UPON RESULTS

Evaluation of the influence on survival of preexisting hepatic disease is complicated by the fact that many patients have more than one diagnosis (Table 17). Ten (14.9%) of our last 67 patients had two coexisting hepatic

TABLE 15. ATTEMPT AT RETRANSPLANTATION IN 27 PATIENTS[a,b]

	No.	Months between first and second transplantation	Months survival after second transplantation
Conventional immunosuppression	21	<1 × 9 patients, 1¼, 2, 2¼, 3, 3¼, 5¼, 6, 12½, 16½, 22½, 27, 29	<1 × 11 patients, 1, 1, 1¼, 1½, 1¾, 2, 6, 12, 13, 16
Cyclosporin—Steroids	6	<1 × 5 patients, 19	<1 × 3 patients, 3½, 6[c], 12[c]

[a] Two of the 27 had third transplantations, 1 and 7½ weeks after second transplantation had failed.

[b] One patient had a chimpanzee heterograft on the second occasion.

[c] Alive.

TABLE 16. TIME OF RETRANSPLANTATION IN SIX PATIENTS WHO SUBSEQUENTLY LIVED FOR >6 MONTHS

OT No.	Duration of first graft	Survival in months after second graft
16	2 months	11
98	5¼ weeks	16
103	22½ months	13
156	2 weeks	6
191	3 weeks	12[a]
209	1 week	6[a]

[a] In cyclosporin series, both alive.

TABLE 17. PATIENTS IN CYCLOSPORIN A SERIES (67 CASES) WITH MULTIPLE DIAGNOSES

OT No.	Main diagnosis	Other diagnosis
176	Cholangiocarcinoma	Sclerosing cholangitis
188	Chronic aggressive hepatitis	Heterozygous α-1-antitrypsin disease
198	Hepatoma	α-1-antitrypsin disease, chronic aggressive hepatitis
206	Tyrosinemia	Hepatoma, diagnosed at previous operation
208	Chronic aggressive hepatitis	α-1-antitrypsin disease
218	Type I glycogen storage disease	Multiple hepatic adenomas
222	Sea-blue histiocyte syndrome	Hepatoma, diagnosed at previous operation
225	α-1-antitrypsin disease (Pi ZZ)	Hemachromatosis
227	Hepatoma	Chronic aggressive hepatitis
234	Hepatoma	Chronic aggressive hepatitis

diseases; however, in most of our analyses (Table 8 to 11), only the most important diagnosis was tabulated.

No disease for which transplantation has been used can be categorically excluded for further trials. This can be appreciated by examination of results with different kinds of disease in pediatric and adult patients before and after the introduction of cyclosporin A (Tables 8 to 11).

Nevertheless, special problems can be expected in treating some hepatic diseases. In the past, some patients with biliary atresia died because of unexpected anomalies which jeopardized performance of a technically satisfactory transplantation (32); specific examples are listed in Table 14.

Noncompliance may be a problem in patients treated for Laennec's cirrhosis. Of our first nine patients with alcoholic cirrhosis, eight died too soon to evaluate this potential problem (123). There were several subsequent successes (Table 9); only one recipient returned to toxic drinking.

THE SPECIAL PROBLEM OF HEPATIC MALIGNANCY

The possibility that immunosuppression may accelerate metastatic tumor growth has been recognized (32). Evaluations of transplantation in treating hepatic malignancies were made in 1981 by Iwatsuki et al. (124) and by Calne (122). Although recurrent disease exceeded 50% in both series, the results did not allow definitive recommendations about continuation of these efforts.

Our case material has been divided into three groups. In the first category were three children whose livers contained malignant tumors (2 hepatocellular cancers, 1 hepatoblastoma) that had not been suspected preoperatively (Table 18). The two recipients who survived operation have no evidence of recurrence after 4¼ to 12½ years. These observations suggest that malignancies can be cured by liver replacement.

In the second category were eight patients, all treated early in our experience, who died less than 1 month after liver replacement for hepatic or duct cell cancer (Table 19). From this case collection, it was possible to determine by autopsy studies the frequency with which extrahepatic tumor spread had been missed in preoperative evaluation. Only 1 of the 8 recipients had metastases.

Twenty-two additional patients, including one (OT 176) whose neoplastic lesion was missed at the initial pathologic examination, lived long enough to evaluate the influence of transplantation upon the malignancy (Table 20). The first 12 were treated in the precyclosporin era; nine recipients developed metastases. A tenth patient with an unclassified sarcoma had extrahepatic metastases at transplantation, and she is well 5½ years later with no clinical evidence of advancing disease. Five patients survived for longer than 1 year; even for those who eventually died of metastases, the extension of useful life seemed to be worthwhile.

Ten more patients have been treated in the cyclosporin era (Table 20). Three had duct cell carcinomas (one with sclerosing cholangitis); one of whom (OT 185) died early without evidence of residual cancer. The second patient (OT 176) died of metastatic cholangiocarcinoma after 1 year. The third (OT 200) is alive in the ninth postoperative month and has metastases. All patients with hepatocellular carcinoma are alive. The tumors were enormous in three cases. In the other four, the lesions were smaller but could not be resected with conventional techniques because of coexisting cirrhosis. It seems likely that selected patients with hepatic or possibly biliary duct malignancies can be effectively treated with transplantation; however, no patient with duct cell carcinoma has ever been cured (53, 122, 124). The prospects may be more favorable for young patients whose hepatocellular cancers could be treated with conventional partial hepatectomy were it not for coexisting cirrhosis.

Heroic efforts may be justifiable for patients with the recently described "fibrolamellar hepatoma" which is

TABLE 18. PATIENTS TREATED FOR ENDSTAGE BENIGN LIVER DISEASE WHOSE REMOVED LIVERS CONTAINED AN UNSUSPECTED PRIMARY LIVER MALIGNANCY AS WELL. ALL WERE TREATED WITH AZATHIOPRINE, PREDNISONE, AND ALG

Patient	Age (yr)	Sex	Primary indication for transplant	Incidentally found liver malignancy	Survival	Tumor recurrence
OT 33	3	F	Biliary atresia	Hepatoma	Alive 12½ years	No
OT 80	7	F	Biliary atresia	Hepatoma	Operative death	—
OT 142	5	F	α-1-antitrypsin deficiency	Hepatoblastoma	Alive at 4½ years	No

TABLE 19. PATIENTS WITH KNOWN PRIMARY LIVER MALIGNANCY WHOSE EARLY DEATH AFTER TRANSPLANTATION PRECLUDED OBSERVATIONS OF THE COURSE OF THE MALIGNANCY. ALL WERE TREATED WITH CONVENTIONAL IMMUNOSUPPRESSION BEFORE 1975

Patient	Age (yr)	Sex	Diagnosis	Survival (days)	Metastases at autopsy and locations	Main cause of death
OT 2	48	M	Hepatoma, cirrhosis	21	No	Pulmonary emboli, sepsis
OT 3	68	M	Bile duct carcinoma (Klatskin's tumor)	8	No	Sepsis, pulmonary emboli, gastrointestinal bleeding
OT 4	52	M	Cholangiocarcinoma cirrhosis	5	Bone, lung, kidney, lymph nodes	Pulmonary emboli, hepatic failure, pulmonary edema
OT 5	29	F	Hepatoma	24	No	Sepsis, bile peritonitis, hepatic failure
OT 6	29	M	Hepatoma	7	No	Hepatic failure, sepsis
OT 7	24	F	Hepatoma	17	No	Pneumonitis
OT 25	45	M	Hepatoma	29	No	Bile peritonitis, sepsis, hepatic failure
OT 79	60	M	Bile duct carcinoma (Klatskin's tumor)	19	No	Hepatic failure due to biliary obstruction

characterized by indolent primary growth and late metastases (125, 126). Three of our last 10 patients with hepatic malignancy have had this diagnosis. In all three, the tumors were massive. In one patient who was treated more than 2 years ago (OT 172), a large tumor thrombus originating in a hepatic vein was extracted at operation from the vena cava and right atrium. He is tumor-free. A second patient, who also is tumor-free after almost 1 year (OT 194), had complete obstruction of the portal vein by tumor. A third patient treated 2 months ago (OT 231) developed recurrence in the residual lateral segment after a right trisegmentectomy 4½ years earlier. The tumor-laden residual segment was replaced with a new liver with a satisfactory result thus far.

At the moment, the prospects for cure seem bleak for patients with duct cell carcinomas, and scarcely better for those with unresectable conventional hepatocellular carcinomas. Patients with smaller malignancies in livers with other diseases, or those with fibrolamellar hepatomas may be more susceptible to treatment.

RECURRENCE OF OTHER HEPATIC DISEASES

In pediatric recipients (Tables 8 and 10), recurrence of nonneoplastic hepatic disease has not been observed. A special feature of transplantation in the younger age group has been the metabolic "cure" of at least five and possibly six so-called inborn errors (Tables 8 and 10) (126–131). With cyclosporin A, the prospects of using transplantation to treat children with a variety of diseases has been heightened because chronic high-dose steroid therapy can be avoided (132).

That the original disease can be recapitulated in homografts was demonstrated in adult recipients. Two patients with Australia antigenemia and chronic aggressive hepatitis redeveloped their original disease and died (133). Other patients with recurrent or newly developing Australian antigenemia have lived for as long as 8 years with the carrier state. It has been our policy to treat HBsAG positive transplant recipients with hyperimmune globulin postoperatively. Antigenemia has returned in every case, sometimes after becoming undetectable for months. With such treatment, Johnson et al. reported permanent antigen clearing in a patient (134).

Recurrent primary biliary cirrhosis (135) as described in the English series was not seen in five grafts studied at autopsy after a few days to more than 6 months, and five patients still living have had no evidence of recurrence in spite of the reappearance of antimiochondrial antibodies in the longest survivors (2¼ and almost 4 years).

We have treated three patients for the Budd-Chiari syndrome. One (OT 174) developed the same disease in the graft and died after 15 months. The terminal course of this patient was triggered by unwise discontinuance of anticoagulant therapy in preparation for a closed liver biopsy. Calne et al. (53) reported a similar occurrence.

THE INFLUENCE OF PREVIOUS OPERATIONS

The technical problems engendered by prior surgery have been so great that the Cambridge-King's College Team consider multiple earlier operations as a relative contraindication to transplantation. However, the majority of candidates evaluated by us and the English workers have had previous operations. The influence of this factor was evaluated in the first 40 patients treated with cyclosporin A and prednisone (Table 21) in whom the results were more analyzable than in our earlier cases.

Fourteen of 40 recipients had major procedures on portal triad structures (Table 21) including six portal-systemic shunts and five biliary duct reconstructions. The risk of death in the first postoperative month was double that in patients with lesser or no earlier operations. There were two operative deaths (OT 176 and 180) (Table 21) including one that occurred while trying to

TABLE 20. PATIENTS WITH PRIMARY HEPATIC MALIGNANCY. THE DIAGNOSIS OF NEOPLASIA WAS KNOWN IN ADVANCE OF TRANSPLANTATION EXCEPT IN OT 176. POSTOPERATIVE SURVIVAL WAS AT LEAST 2 MONTHS FOR ALL BUT ONE PATIENT

Patient	Age (yr)	Sex	Diagnosis	Survival (months)	Metastases	Malignancy factor in death
			Precyclosporin Era			
OT 8	1 1/12	F	Hepatocellular cancer	>13	Brains, lungs, liver, other abdominal organs	Main
OT 14	16	F	Hepatocellular cancer	>14	Diaphragm, retroperitoneal space, liver, pancreas	Major
OT 15	43	M	Hepatocellular cancer, cirrhosis	>11	Lungs, liver, diaphragm	Main
OT 23	15	M	Hepatocellular cancer	>4	Brain, lungs, liver, retroperitoneal space	Main
OT 26	11	F	Biliary atresia, hepatocellular cancer	>2	Lung	None
OT 45	53	M	Hemangioendothelial sarcoma	>2	Brain, lungs, liver, spleen, pericardium, peritoneum, stomach, pancreas, kidney	Main
OT 78	48	M	Bile duct carcinoma (Klatskin's tumor)	>24	Liver, bile duct at reoperation. No autopsy	Main
OT 90	41	M	Bile duct carcinoma (Klatskin's tumor)	>54	Bile duct, liver, duodenum at reoperation No autopsy	Main
OT 102	51	F	Bile duct carcinoma (Klatskin's tumor)	>2	None	None
OT 111	9	F	Tyrosinemia, hepatocellular cancer	>3	Microscopic metastasis in the lung and paraaortic lymph nodes at autopsy	Minor
OT 114	27	F	Sarcoma (undetermined cell type) of liver invading diaphragm, metastasis to right lung and peritoneum	>68 (Alive)	Grossly fine intraabdominal and pulmonary metastases at time of transplantation which have been quiescent for 5½ years	Alive
OT 121	32	F	Hepatocellular cancer	>5	None	None
			Cyclosporin Era			
OT 172	24	M	Hepatocellular cancer[a]	>27	None	Alive
OT 176	33	F	Sclerosing cholangitis, duct cell carcinoma[b]	>12	Liver, duct, peritoneum	Main
OT 185	56	M	Duct cell carcinoma (Klatskin's tumor)	>½	None	None
OT 194	26	M	Hepatocellular cancer[a]	>11	None	Alive
OT 198	47	F	α-1-antitrypsin disease, cirrhosis, hepatocellular cancer	>9	None	Alive
OT 200	27	M	Duct cell carcinoma (Klatskin's tumor)	>8	Liver, operative wound	Alive
OT 206	2	F	Tyrosinemia, hepatocellular cancer	>7	None	Alive
OT 227	53	M	Cirrhosis, hepatocellular cancer	>3	None	Alive
OT 231	23	F	Hepatocellular cancer[a], previous right trisegmentectomy	>2	None	Alive
OT 234	24	F	Hepatocellular cancer, cirrhosis	>1	None	Alive

[a] Fibrolamellar.

[b] Diagnosis of cancer missed in surgical specimen, but diagnosed at surgical margin and within the native liver by reexamination 9 months later.

TABLE 21. INFLUENCE OF PREVIOUS MAJOR HEPATOBILIARY SURGERY[a] UPON RESULTS IN 40 CONSECUTIVE CASES (CYCLOSPORIN ERA)

	No.	Survival (months)		
		>1	>2	>6
Previous major operation(s)[a]	14	10	10	10
No major operation[b]	26	22	21	19

[a] Six portal-systemic shunts (5 portacaval, 1 distal splenorenal), 5 bile duct reconstructions, and 3 portoenterostomies (Kasai).

[b] Previous exploration, open liver biopsy, cholecystectomy, T-tube insertion, and splenectomy were not counted as major prior procedures although the resulting vascular adhesions were usually troublesome. Twelve of the 26 patients had one or more of these "minor" previous operations including 4 cholecystectomies, 3 T-tube insertions, and 1 splenectomy.

take down a portacaval shunt. The portal vein after portacaval shunt (especially side to side) may have suboptimal length and can be so sclerotic that suturing is difficult or impossible. For patients who survive the first postoperative month, the background of previous major operations was no longer a factor (Table 21). These results suggest that a prudent decision may be against transplantation in patients with a complex surgical history, but that a "clean abdomen" is not a criterion of selection.

THE OPTION OF AUXILIARY LIVER TRANSPLANTATION

The alternative to orthotopic liver transplantation is transplantation of an extra liver (auxiliary transplantation) without removal of the diseased native organ. Clinical trials have been discouraging, as summarized by Fortner et al. (136) from the compiled world experience. Of nearly 50 well-documented auxiliary transplantations, only one was an unequivocal success. Subsequently a report from Paris described a second success (137).

Our opinion has been that auxiliary liver transplantation should be restricted to patients with potentially reversible liver disease. In such a situation, the extra liver could be construed as a temporary support organ which can be removed later. However, we have encountered increasing numbers of patients whose portal vein has clotted in the hepatic hilum, making it technically impossible to consider liver replacement. Other candidates are those with extensive previous surgery in the right upper quadrant. Such patients can theoretically be helped by an auxiliary liver transplantation, particularly when the superior mesenteric vein or other distal tributories to the main portal circulation are still open. The optimal conditions for vascularization of an auxiliary liver graft require input from the portal circulation (2, 32, 138, 139), largely because of its high concentrations of endogenous hormones.

DETERMINANTS OF THE FUTURE

The Question of Financing

Through 1980 in the United States, almost all liver transplantations were performed in the Clinical Research Centers (CRC) supported by the National Institutes of Health. The fraction of the per case cost born by this government agency shrank from year to year because of the increasing willingness of many third party insurance carriers to pay for part or all of the service. Third party payments were collected by the institution and remanded back to the National CRC headquarters which included such collections as part of the total grant funding. In the last years of the program at the University of Colorado, approximately 85% of CRC expenditures for liver transplantation were paid for in this way. By having CRC support for the other 15%, it was not necessary to screen candidates for their ability to pay. This creative practice of federal and private cost sharing was conceived and made practical by Dr. William DeCaesare, Director of the Clinical Research Center Division, Bethesda, Md. Thanks to the administrative leadership that flowed from DeCaesare's office for more than 2 decades, almost all modern-day techniques of immunosuppression and transplantation of all organs, beginning with the kidney, were developed on CRC units.

However, it is not reasonable to look indefinitely to the CRC for support. So far, none of the liver recipients at the University Health Center of Pittsburgh has been treated on the pediatric or adult CRC. The principal financing for their care has been from health insurance programs or, less commonly, from private sources including community fund raising. The collection rate for bills has been greater than in the Colorado experience. With the exception of Blue Cross/Blue Shield and some health maintenance organization programs, the major health insurance companies have willingly accepted their responsibility for liver transplant candidates providing they were forewarned. The patterns of support from Blue Cross/Blue Shield have been irregular, probably because of their close association with MediCare.

It is ironic that government decisions or opinions have impeded the movement of liver transplantation to the private sector of medicine. A pronouncement by a state or federal official of MediCare to the effect that liver transplantation is "experimental" and not fundable has often been the basis for a similar decision by regional officials of Blue Cross and/or Blue Shield or by a cost-conscious health maintenance organization. Even so, a rapidly growing number of state (or Blue Cross) agencies (including those in Pennsylvania, New York, and New Jersey) have classified liver transplantation as a service.

In spite of the advantage of a preexisting federally funded organ procurement network in the United States as part of the End Stage Renal Disease Program, the financing of liver procurement is not on a solid base. There are no formal guidelines about how to proportion the extra costs of removing extrarenal organs from a multiple organ donor, or how to ensure against the potential malpractice and other liability that could be incurred. Etna Life Insurance Company, the carrier for the National Kidney Procurement Program, recently drew attention to these policy gaps in a document that had a chilling effect on some transplant coordinators.

The approximate average cost of a liver transplantation in Pittsburgh has been $55,000 (range $23,000 to $150,000). The procedure offers hope of genuine rehabilitation. Dying of endstage liver disease with no hope of real recovery may be even more expensive. O'Donnell et al. (140) reported from Boston that the average cost of nonsurgical treatment of patient for variceal hemorrhage was $35,000. The use of any operative procedure increased the total to $53,000. In many of our patients, the expenses incurred during repeated hospitalizations before transplantation dwarfed those incurred by transplantation itself.

The Potential Influence of Transplantation Upon the Practice of Hepatology

Five to 10 years from now, we believe that every major center for the treatment of liver disease will have either transplantation capabilities or direct access to this kind of service. The surgical techniques are within the grasp of many practicing surgeons. The frequency with which liver transplantation can be used will be great although this has not been properly assessed. Our estimate is that at least 20 centers will be required in the United States.

Knowledge that the provision of new liver tissue is a realistic objective at the end of the line will influence decisions about treatment. It will be increasingly important to avoid major and often futile surgical operations that jeopardize ultimate candidacy for transplantation. Fortunately, there are alternative approaches. Sclerosing therapy for the control of variceal hemorrhage instead of portal diversion has become increasingly accepted. "Interventional radiologists" often have been able to ameliorate duct strictures in sclerosing cholangitis and other diseases as effectively as can surgeons at open operation. When procedures such as porticoenterostomy (Kasai) are performed in infants with biliary atresia, it will be worthwhile to avoid deviations from the standard Roux-Y technique and multiple reoperations which make transplantation difficult or impossible.

The presence of regional units undoubtedly will move the timing of transplantation forward in the course of the disease. The fact that there has been a very high preoperative mortality of patients accepted as candidates for new livers is an indication of the lateness of referrals. Throughout the years, many others have reached the operating room in such appalling condition that there was little hope of survival.

An avalanche of new scientific information should become available to hepatologists and surgeons as the result of progress in transplantation. Much has already been learned about the synthesis of proteins whose origin was not previously clear (2, 9, 141–143). Further improvements in surgical techniques and immunosuppression will increase the harvest. The history of medicine is that what was inconceivable yesterday and barely achievable today often becomes routine tomorrow.

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Mr. GORE. Dr. G. Melville Williams, in addition to being professor of surgery at Johns Hopkins Hospital and a distinguished surgeon, is president of the American Society of Transplant Surgeons.

Dr. Williams, you, too have gone to a special extreme to be with us today, rearranging your travel plans to Holland where you were scheduled to appear before the International Congress on Organ Procurement today. We appreciate the extra effort, and we look forward to your testimony.

Dr. G. MELVILLE WILLIAMS. Thank you, Mr. Gore.

It is possible to summarize national efforts in kidney transplantation using round numbers, which are easier to remember somewhat more than 5,000 kidney transplants were performed last year; of these, 30 percent of the kidneys came from related living donors; 3,300 kidneys can be expected to provide life-sustaining function; 2,500 individuals may be expected to return to work or to premorbid social activity; and, soberingly, 500 individuals die.

The key point is that through kidney transplantation with existing knowledge, one-half of the individuals transplanted return to work, or their state of health before they got sick.

The analysis of data acquired by many collaborating centers show that five variables have influenced the degree of success. These variables are the center—some centers have excellent results and some not so good—second is the number of blood transfusions given the perspective recipient prior to transplantation; third is the use of antilymphcitic serum; fourth, whether or not the kidney functions immediately after transplantation; and fifth, the degree of matching of donor and recipient. Knowledge of the influence of these factors has been harnessed by most transplantation centers with an improved overall national success rate increasing from 48 percent to close to 60 percent in the past year in organs recovered from cadaver donors.

It is interesting to note at this point that what has been considered traditionally as a therapeutic endeavor, namely kidney transplantation, reports results that are inferior to the results reported by Dr. Shumway for heart transplantation, and slightly inferior to the results that Dr. Starzl has published on liver transplantation. It should be acknowledged that, in kidney transplantation, we have, except for four centers, been unable to use the immunosuppressive agents available for use in these nonrenal transplants. The point is that we have to redefine our concepts of what is experimental and what is not.

In the past, there has been some concern that patients with kidney failure were denied access to transplantation systems. Virtually all patients enter the system after having their lives sustained by dialysis. Thus, referral to a transplant center is entirely dependent upon the perception on the part of the patient and the nephrologist caring for him that transplantation offers distinct advantages. With results improving and with the prospect of a real breakthrough in the near future, this problem, I believe, will be diffused and unimportant. Patients awaiting transplantation are registered with the transplant center and undergo tissue typing and screening for the presence of antibodies in their serum. The presence of these antibodies informs the transplant surgeon that the patient has had exposure to human tissues and has developed some immunity to them through blood transfusions, pregnancies, or other transplants.

Four centers in this country have had experience with the new immunosuppressive agent, cyclosporine, in attempts to suppress rejection in renal allografts. All investigators agree that many of the practices we have applied may prove to be obsolete when this drug becomes available for general use, hopefully by the end of June or the first part of July. This drug, used in combination with small doses of Prednisone, promises to provide us with 80 to 90 percent rates of success in cadaver donor transplants. The early concerns about the development of cancer and of the potential toxicity of the drug to the kidney itself have been ameliorated to some extent by more recent experience.

Thus, the field of kidney transplantation is excited and restless awaiting the availability of cyclosporine. As a nation, it behooves us to plan our national strategy. I foresee four major problems confronting us. First, research funding; second cost containment; third, data acquisition and analysis; and fourth, increasing the rate of organ donation—the fourth being the most significant.

It may be surprising to some of you in this room to know that we are considerably behind our European colleagues in the application of a crucial histocompatibility locus in tissue typing. It may be disconcerting to know that we do not know how to characterize our black patients in terms of their tissue typing makeup nearly as well as we how to characterize our Caucasian patients. Further, if we could reliably preserve livers, lungs, hearts, for a period of 12 to 24 hours, considerable savings could be achieved in eliminating the need for charter jet travel between the city identifying a heart or liver donor and the transplantation center.

With respect to the kidney itself, where most of us feel the preservation problems are pretty well solved there is in fact the reality that 25-45 percent of the kidneys transplanted fail to function immediately—and this may be a very important point when using the new agent cyclosporine—it has some deleterious effects on the kidney—so without a monitor of toxicity, that is, some baseline renal function, our success rates may well be jeopardized.

I wish to address the problem of cost and make two points. First, there is the widespread notion which I think we should roundly defeat that any new therapy is apt to be costly therapy. Regrettably, this may be true in some instances, but in many others, this is a very short-sighted view. As Dr. Starzl has already pointed out, the treatment that we commonly give patients with liver failure may be more expensive than the process that cures them.

In the case of transplantation, there was a recent directive from the Health Care Financial Administration that it would not pay for purposeful blood transfusions between a potential living donor and the potential recipient of the kidney, a process which has led to 90 percent graft success, even in mismatched donor-recipient pairs. The cost of giving the blood transfusion is one-third the cost of one dialysis treatment.

Support must be given to agencies such as the Office of Technology Assessment to develop a much more reasoned approach in our application and evaluation of new methods of therapy and means of financial reimbursement in this whole field of transplantation.

The second point regarding cost and transplantation is that, purely in economic terms, long-term disability associated with expensive therapy costs more than death, which costs more than a cure. One can do some simple calculations regarding the expenditures required to sustain a disabled individual on hemodialysis. We, the taxpayers, pay for the medical therapy and the social security benefits accrued to the individual. We also lose taxes from the loss of income. In the event of death, we are faced with paying social security death benefits and we lose income from taxes. But in the case of cure, we pay for medical therapy alone and recover money from taxes in gainful employment.

As academicians, we commonly view our substantial rate of failure in kidney transplantation as the principal cost. However, recently, Dr. Krakauer, in analysis of data at the NIH, has shown through mathematical models that even if we increased the rate of success of cadaver transplantation to 90 percent, we will do very little to reduce overall costs of treating the patient with kidney failure because the costs are principally related to chronic hemodialysis. The only way costs can be substantially reduced nationwide is to increase the number of transplants performed, and I would suggest that a target goal would be to double the number of transplants in the next 5 years.

As we are now poised to enter a new era in clinical transplantation, it is important to know on a timely basis how we are performing. Despite the carefully conducted trials with cyclosporine, difficulties may be encountered which are entirely unexpected. Our current system of acquiring data—and this may help with the question raised by our Congressman—is to obtain it from the transplant centers via the networks that then forward the verified data to the Medical Information System within the Health Care Financing Administration. I have worked with this group. They are intelligent, interested, highly-informed and hard-working people.

But those that are required to collect the data and assess it are poorly supported monetarily. For example, any form that is distributed as a questionnaire to gain information must be processed through OMB. This takes time. And any correction of that form, such as searching for new toxicities related to cyclosporine, for example, must go through the same process. So, between the time we ask the question and get the answer, an enormous period has lapsed and there will be no way to generate data on a national scale without creating, I think, legislatively some funds to support this either within the government or arranging contracts to independent and interested individuals, such as Dr. Paul Tarasaki who has maintained an ad hoc registry without due reimbursement for long periods of time.

Lastly, and most importantly, there is this problem of increasing the number of transplants performed. There has been a steady increase, as I mentioned, from 4,721 transplants 4 years ago, to 5,358 in 1982. However, this trend cannot possibly meet the demand created by improved results.

At one time—and I guess this was about 15 years ago—a study was done which estimated that 50,000 individuals might die in the United States each year at any age and of a disease compatible with organ donation. A more recent conservative estimate places this figure at 20,000. This is still immaterial, considering that only 2,000 become actual kidney donors. Is the reason for our failure to obtain more organs the result of negative public attitudes or inefficient procurement systems? I think both.

With respect to attitudes, virtually every poll has indicated that the majority of the American people are willing to donate parts of their body for transplantation if the results are good. However, the mechanisms for opting into the system of organ donation are sufficiently complex that, for example, in the State of Maryland, one has to have two witnesses in order to sign an organ donor card to put on your driver's license. At least 98 percent of the people requested to do so have failed to sign up as organ donors. We have never been called in a single instance from any emergency room in which they have identified an individual with a card on their person and asked us to proceed with organ removed for transplant.

From the organ procurement systems point of view, the decision for organ donation is requested at the wrong time. When death is sudden and accidental, there may be no time to locate and approach the family and no organs are removed. In a great majority of instances, a family confronted with grief is asked to make another contribution, and 30 to 75 percent of the families, when requested, say no.

The role of the Government is, I think, very complex and controversial. In a sense, we as a society have deemed that all patients having kidney failure may be treated, and we pay for it. It is also likely that the best treatment is kidney transplantation. Yet, while all individuals would favor this type of therapy for themselves, we consider attitudes favorable toward transplantation if a mere 60 percent canvassed state that they are favorably included toward organ donation. It is what I call the "Henny-Penny" syndrome, where everybody wants to eat the bread and nobody wants to plant the wheat. In the particular case of organ transplantation and organ donation, the decision, pro or con, has to be made by individuals at some point removed from the immediate grief of the circumstances of death.

If it is in the best interest of society to obtain the bullet in order to find the murderer, I might ask, is it not also in the best interest of society to obtain kidneys, hearts, livers, and pancreases to save the lives and relieve the suffering of other individuals? In the case of the bullet, the family has no option to deny autopsy and dismemberment. In the case of the heart and the liver and the lung, the family persists in having the right, and we would defend that right. But you see how discrepant we are in our circumstances.

Most recently in California, a law was passed which I hope receives due attention, and that is that, in cases that would come to autopsy by the coroner or medical examiner, the coroner would be empowered to remove the cornea unless there was expressed dissent. So, from the ethical point of view—and I should add that similar laws are present in Maryland, Florida and West Virginia. (Maryland was the first State to pass such a law, I believe). The decision has been made in favor of presumed consent. Yet, if we were to proceed with this, normally I think it would shell shock our Nation. So we have to proceed cautiously.

In Colorado, a State law exists demanding an individual to say yes or no at the time of applying or renewing a driver's license. The individual cannot ignore the question, I believe. So there is coercion brought to bear on making the decision. At this stage, this would be all, I think, that society would be willing to go with, and I suggest simply that everybody think about this and make a decision for their own personal use in writing to have on their person.

In conclusion, I want to just make three points: The results of kidney transplantation are improving and will improve further; there is still the need for research, particularly in the field of organ preservation; and a breakthrough is necessary for organ donation to be viewed as normal and natural by the public. When this occurs, we can truly celebrate a new era.

Thank you.

[The prepared statement of Dr. G. Melville Williams follows:]

KIDNEY TRANSPLANTATION 1982

THE STATE OF THE ART AWAITING A BREAKTHROUGH

It is possible to summarize national efforts in kidney transplantation using round numbers as follows: somewhat more than 5,000 kidney transplants are performed per year; of these, 30% of the kidneys come from related living donors; 3,300 kidneys can be expected to provide life sustaining function; 2,500 individuals may be expected to return to work or to premorbid social activity; and 500 individuals die.

The analysis of data acquired by collaborating centers show that five variables influence the degree of success. These variables are: the center performing the transplant; the number of transfusions given the perspective recipient prior to transplantation; the use of antilymphocytic serum to augment immunosuppressive treatment; the degree of matching of donor and recipient; and whether or not the kidney functions immediately after transplantation. Knowledge of the influence of these factors has been harnessed by most transplantation centers with an improved overall national success rate increasing from 48% to close to 60% for cadaver donor kidneys.

In the past there has been concern that some patients with kidney failure were denied access to the transplantation system. Virtually all patients enter the system after having their lives sustained by dialysis. Thus, referral to a transplant center is entirely dependent upon the perception on the part of the patient and the nephrologist caring for him that transplantation offers distinct advantages. With results improving and with the prospect of real breakthrough in the near future, this problem, I believe, will be diffused. Patients awaiting transplantation are registered with the transplant center and undergo tissue typing and screening for the presence of antibodies in their serum. The presence of these antibodies informs the transplant surgeon that the patient has had exposure to human tissues and has developed some immunity to them through blood transfusions, pregnancies, or other transplants.

There is great variation in the organization of transplant centers. Historically, transplantation was an acknowledged experimental procedure which could be performed only in hospitals affiliated with strong university programs. In a given metropolitan area in the east, there may be four or five active transplant centers vying for the treatment of patients. In other areas particularly in the mid and far west, there may be only one transplant center providing services to an enormous population. The location of the center and how crowded it is with other centers determine practices and the need for collaboration. In order to perform transplants, every center must have some means of obtaining transplantable organs and of determining the degree of match and the likelihood of success if a given organ is used for a given patient. If a center is treating 600 dialysis patients awaiting transplantation, clearly it can develop efficient organ procurement programs, tissue typing laboratories, community education programs, etc. If a transplantation center is serving the needs of 100 patients awaiting transplantation, it must affiliate with other centers, for the kidneys it obtains are frequently incompatible with its own patients.

Four centers in this country have had experience with the new immunosuppressive agent, Cyclosporine, and all of these investigators agree that many of the practices we have applied may prove to be obsolete when this drug becomes available for general use. The drug used in combination with small doses of Prednisone promises us with 80 to 90% rates of success in cadaver donor transplants. The early concerns about the development of cancer in long-term recipients and of the potential toxicity of the drug to the kidney itself have been ameliorated to some extent by more recent experience. Cyclosporine will not abrogate existing antibody levels from previous exposure so that some individuals awaiting transplantation may wait long periods of time before a donor is identified to whom the patient is not immunized. For these patients and for others who have a concerned family member, related living donor transplantation is a valid option. A second breakthrough has occurred in this area, namely that of using blood drawn from the potential donor given to the potential recipient as a means of conditioning the recipient for the kidney transplant. Recipients who have sustained three small blood transfusions from their potential donor have enjoyed 90% graft survival rates despite being imperfect tissue matches. This degree of success has led to greater numbers of volunteer donors and may even lead to successful grafts between a husband and a wife, for example.

Thus, the field of kidney transplantation is excited and restless awaiting the availability of Cyclosporine. As a nation, it behooves us to plan our national strategy as we apply these technological advances. I foresee four major problems confronting us: 1) research funding; 2) cost containment; 3) data acquisition and analysis; and 4) increasing the rate of organ donation.

While we anticipate substantial improvement in graft and patient survival in the near future, it must be acknowledged that the long-term effects of Cyclosporine are not known, and there still must be more precise means for controlling the immune response. Basic scientists in immunology have developed exquisitely specific means for monitoring and controlling some immune responses. This technology using monoclonal antibodies has yet to be harnessed in clinical transplantation.

It may be surprising to some to know that we are three years behind our European colleagues in attempting to match donor and recipients for the Dr antigen system which promises to be more important than the systems commonly in practice. We know much less about how to characterize Blacks for tissue typing, and we know very little about how to extend the period out of the body for organs other than the kidney. If we were able to preserve these organs reliably for periods of 12 to 24 hours, considerable savings could be achieved by eliminating the need for charter jet travel between the city identifying a heart or liver donor and the transplantation center. With respect to the kidney itself, much is known about preservation. Yet, 25% of cadaver kidneys fail to function immediately after transplantation and this is very important when using Cyclosporine. As a nation, we have decried the expense of caring for patients with kidney failure while forgetting that research and development funds are always necessary to provide better solutions.

The problem of cost containment is one that concerns many of us in transplantation and there are two points to be made. First, there is a widespread notion that new therapy is costly therapy. Regrettably, this is true in many instances, but in many others it is quite short-sighted. For example, there was a recent directive from the Health Care Financing Administration that it would not pay for purposeful blood transfusions in the living donor situation described. The charge for drawing a unit of blood and dividing it into thirds for subsequent transfusion is one-third the charge of one dialysis treatment and the result may be a 90% successful outcome of the transplant. Support must be given to agencies such as the Office of Technology Assessment to develop a reasoned approach in the application and evaluation of new methods of therapy and means of reimbursement in the field of transplantation. The second point regarding cost and transplantation is that in purely economic terms, long term disability associated with expensive therapy costs more than death which costs much more than a cure. One can do some rather simple calculations regarding the expenditures required to sustain a disabled individual on hemodialysis. We, the taxpayers, pay for the medical therapy and the social security benefits accrued to the individual. We also lose taxes from the loss of income. In the event of death, we are faced with paying social security death benefits and we lose income from taxes. In the case of cure, we pay for the medical therapy but recover money from taxes.

As academicians, we commonly view our substantial rate of failure as the principal cost in transplantation. Recently, Dr. Krakauer at the N.I.H. has shown through mathematical models that even increasing the rate of cadaver donor transplant success to 90% will do very little to reduce overall costs of treating patients with kidney failure. The only way costs can be substantially reduced is by increasing the number of transplants performed.

As we are poised to enter a new era in clinical transplantation, it is important to know on a timely basis what our performance is. Despite the carefully conducted trials with Cyclosporine, difficulties may be encountered which are entirely unexpected. Our current system of acquiring data through the End Stage Renal Disease Networks and from the networks into the Medical Information System of HCFA is poorly supported. As a group, the individuals responsible for the creation of the forms and for their collection and analysis are highly motivated, intelligent and hard working. Yet, the system lacks monetary commitment and quick response. For example, in order to modify the forms and acquire new information regarding Cyclosporine toxicity, a process involving OMB must be engineered. One recommendation we can all make to this committee is that a stable data acquisition and analysis group be formed. This duty can be performed by the private sector through contract mechanisms as well as by creating a division within a given government agency.

Finally, there is the problem of increasing the number of transplants performed. There has been a rather steady increase over the last four years from 4,721 to 5,358. This trend if continued will not meet the demands created by improved results. At one time, it was estimated that as many as 50,000 individuals might die each year at an age and of a disease compatible with organ donation. A more recent conservative estimate places this figure at 20,000. This is still immaterial considering that only 2,000 become actual kidney donors. Is the reason for our failure to obtain more organs the result of negative public attitudes or inefficient procurement systems? I think both.

With respect to attitudes, virtually every poll has indicated that the majority of the American people are willing to donate parts of their body for transplantation. However, the mechanisms for opting into the system of organ donation are sufficiently complex that only 2% of the individuals given the opportunity at the time of signing their Driver's License in the

State of Maryland become organ donors. From the organ procurement systems point of view, the decision for organ donation must be made at the time of death and the decision is made by relatives not the individual. When death is sudden and accidental, there may be no time to locate and approach the family and no organs are removed. In a great majority of instances, this is the wrong time to make a rational decision, and 30-75% of the families say no.

The role of government in altering our system particularly our timing to make this important decision of organ donation remains most controversial. In a sense, we as a Society have deemed that all patients having kidney failure may be treated. It is also likely that the best treatment is kidney transplantation. Yet, while all individuals would favor this type of therapy for themselves, we consider attitudes favorable toward transplantation if a mere 60% canvassed state that they are favorably inclined toward organ donation. As a Society, we have denied individuals the right to decline autopsy in cases of homocide, suspected suicide and in some accidental deaths. If it is in the best interest of Society to obtain the bullet in order to find the murderer, is it also not in the best interest of Society to obtain kidneys, hearts, livers, pancreas, etc. to save the lives and relieve the suffering of other individuals? In certain states, laws have been passed enabling the coroner's office to remove the cornea, unless there is expressed dissent, for transplantation from bodies that will be autopsied. Thus, we are entering into an area where the ethical position has already been clarified. What has to happen from now on is a gentle boost in public consciousness together with properly timed coercive steps. I have in mind a goal demanding individuals to state yes or no to organ donation at the time they renew their Driver's License without the need for witnesses and with full legal recognition that a transplant surgeon may proceed to remove organs from an individual carrying a "yes" card without the fear of prosecution.

It is likely that an ever increasing demand for transplantable organs will focus public awareness and agreement so that what appears to be coercive now will not be in two years. It is my hope that greater interest in death and dying and the continuation of life will be addressed in medical and pastoral education. Because organ donation is a salutary and comforting process for families, it is our obligation to take away the agony of the decision at a time of maximal grief and provide them with the knowledge that something positive has come from such a tragedy. I believe that this will become a new responsibility of every transplant service.

In conclusion, there are three points to be made: 1) the results of kidney transplantation are improving and will improve further; 2) there is still the need for research, particularly in the field of organ preservation; 3) a breakthrough is necessary for organ donation to be viewed as normal and natural by the public. When it occurs, we can truly celebrate a new era.

Mr. GORE. Thank you, Dr. Williams.

I suppose the single most important thing that could be done to help solve the problems that you three doctors encounter is for American citizens to say to their family members in conversation that, "If tragedy ever occurs and I am in a situation where my kidneys or heart or lungs or liver could help someone else to live, I would want you, as my next of kin, to make those organs available." Is that the single most important thing that could happen?

Dr. SHUMWAY. Yes.

Dr. STARZL. Yes.

Dr. G. MELVILLE WILLIAMS. Yes.

Mr. GORE. How many lives—let's say, for example, that today or tomorrow people in this country had conversations around the breakfast table or the dinner table and said to each other, "Look, let's agree as a family we think this is important. This will be our policy as a family." Let's just imagine that every American in the country did that, and you didn't encounter that obstacle, how many lives would you estimate you could save as a result?

Dr. G. MELVILLE WILLIAMS. Thousands. If we can raise public consciousness to the extent where they make the demands of the physician taking care of their loved one during the dying process, as is happening—this is beginning now—then we really will have made a big step. Part of the problem is the problem with the doctor identifying and engaging the donor and the family in the process of organ donation, I believe.

Mr. GORE. So doctors and nurses and hospitals have a role to play in making families aware of what the opportunity is for hope and joy to be born of tragedy and for them to make available organs that are greatly needed to sustain life elsewhere. Do you find that many doctors and nurses and hospitals just aren't aware of how great this need is?

Dr. STARZL. I think it is a double problem. I think perhaps the doctors and the nurses are aware of it, but it is a kind of a positive or affirmative action that can easily be cancelled if the lay public doesn't reinforce. And I think it works the other way around, that if the lay public will take the first step, then the physicians and nurses will reinforce that. But they have to work together.

This syndrome that has been described of the families demanding that organs be used and really bringing it up for the first time is becoming very common. But I have seen it, going back for 20 years. It really was how the whole organ donation concept came into being in the first place. Interestingly enough, some of the first cases that I remember were children of physicians who did not want that vital resource to go to waste and having now realized that their child was brain dead.

Mr. GORE. These other problems which we will be attacking are likely to have less impact on the solution to the problem, of the overall problem, than that raising of awareness among the American public about how important this is. But they need to be solved, too, these other matters, and in the process of solving them, we may be able to contribute to making people more aware of how important organ donation is.

Let me just briefly give you my thumbnail understanding of what this situation is and ask you to agree or disagree. No. 1, through a combination of your skill and the accumulated knowledge in the medical profession and this remarkable new drug called cyclosporine A, which is the latest and most important in a series of measures that make rejection almost a thing of the past, we have entered a new era of organ transplantation; there is no question about that, is there?

Dr. **Starzl.** No.

Dr. G. **Melville Williams.** No.

Dr. **Shumway.** No.

Mr. **Gore.** The public is quite aware of the efficacy of kidney transplants. But, in fact, Dr. Starzl, there are as many cases of end-stage liver disease as there are of end-stage kidney disease—almost as many—are there not?

Dr. **Starzl.** I think it is in that order of magnitude, or perhaps it would be two-thirds as common as end-stage renal disease. But hepatic disease is the fourth leading cause of death in the United States at the present time, or it ranges between third and fifth.

Mr. **Gore.** So the potential for the successful procedure you have pioneered is equal to the potential—or nearly equal to the potential—of kidney transplantation?

Dr. **Starzl.** It is going to have a broad application. I don't think there is any doubt about it.

Mr. **Gore.** Now, the reason the public awareness of liver disease does not approach the public awareness of kidney disease is that there is no equivalent for dialysis that keeps large numbers of liver patients alive for many years, they die if they don't get a transplant.

Dr. **Starzl.** Yes; Mr. Skeen brought back sad memories, as I already said, of 20 years ago. In 1962, chronic artificial kidney treatment was available for six patients in the United States and in the world. Those six patients were all at the University of Washington under Scribner, where the technology of chronic artificial kidney treatment was really just coming out. That is the way things were then. But, of course, that changed.

As Dr. Shumway said, I don't think the prospect of changing with hearts or with livers, where the functions are even more complex, is really a realistic hope for the immediate future, or perhaps ever. That means that the urgency for the organs that we are looking for now is far greater than it is for the kidney, and it will probably continue to be that way.

I think that no renal donor should fail to be considered for the need of extra-renal organs on the spot. I think that is an important thing, and the transplant coordinating groups, I believe, are really working on that.

Mr. **Gore.** It is certainly a tragedy that demands a response.

I wonder if I might just ask people to raise their hands. How many parents or close relatives of children in these circumstances just heard about these hearings today and came out? Could you raise your hands?

[Show of hands.]

Mr. **Gore.** There are several people. I noticed several children in the audience. Thank you.

I know that we have had circulated to us a number of pleas from families for assistance from all over this country.

The label "experimental," isn't accurate when applied to either liver transplants or heart transplants; would both of you agree?

Dr. **Starzl**. Absolutely. Or heart-lungs.

Mr. **Gore**. Let's talk about heart-lungs for a second. The reason you transplant the combination of lungs and heart—it is triggered by the need to transplant the lungs—but if you transplant the the lungs alone, you cannot accurately monitor the onset of rejection.

Dr. **Shumway**. Correct.

Mr. **Gore**. But by transplanting both the lungs and the heart as a system, you can put in a catheter that allows you to monitor and control the rejection process and get roughly the same success rate as you do with the heart alone; is that correct, Doctor?

Dr. **Shumway**. That is correct.

The X-rays after a lung transplantation are so ambiguous that one wouldn't know whether it was rejection or atelectasis or pneumonia or pulmonary edema. But with the heart on the system as the monitor of these events, then we can, by taking a little piece of the heart out in a very simple manner, look at it under a microscope, and tell exactly what is going on with respect to the health, not only to the heart, of course, but of the lungs as well. So this has made the whole thing extremely feasible. I think it has outmoded completely any future application of unilateral lung transplantation.

Mr. **Gore**. I see.

So the label of "experimental" is just inappropriate today?

Dr. **Shumway**. I think it is a convenient label to use for anything that the third-party carriers or the Government doesn't wish to support financially.

Mr. **Gore**. Yes. That is laying it on the line, Doctor.

You said something astonishing in your testimony, that you haven't had a single case of rejection?

Dr. **Shumway**. Rejection that is notable from the standpoint of clinical inspection or examination of the patient. The only way with cyclosporine A that we have been able to tell if there is a rejection process going on is through the biopsy of the heart.

Mr. **Gore**. I see. That allows you to calibrate the amount of the drug that is used.

Dr. **Shumway**. Right. And it allows us to intervene at a time which is much earlier than in the past, before any severe damage to the transplanted organ has occurred.

Mr. **Gore**. I understand this drug was discovered by Sandoz Laboratories having a policy of having its employees bring back soil samples from vacations; is that correct?

Dr. **Shumway**. That is what I understand, yes.

Mr. **Gore**. And one of them came back with a soil sample from somewhere in Scandinavia and they ran it through the tests and just discovered this in the ground somewhere?

Dr. **Shumway**. That is right. Then it was applied experimentally in Cambridge, and then clinically as well, and it is now available, and I was surprised to hear, in only four renal transplant units. I didn't understand that at all.

Dr. **Starzl**. In Cambridge, the drug began to be used in the late spring or early summer of 1978. It was released in this country to the group at Harvard and to us for kidneys in late 1979, and then

Houston and Minnesota about 9 months after that. So those are the four.

There is a multicenter trial going on in Canada, however, and a multicenter trial in Europe, the results of which, in both instances, have been reported and showing a marked advantage for the cyclosporine.

Mr. **Gore**. So that has made rejection virtually a thing of the past. It still has to be monitored carefully and watched, but, as a source of failure, it is virtually a thing of the past.

Dr. **Starzl**. It has certainly been enormously reduced. It has just about doubled the survival of organs it has been used for.

Mr. **Gore**. I know that there are still some questions that have to be answered about potential side effects, but this is truly a miracle drug and, combined with your magnificent skill and the advances in the medical profession generally, we have created—you have created—a new era for transplant patients. As you said, Dr. Williams, we desperately need a national strategy for coping with the onset of a remarkably increased demand for organs for transplantation, and we have a bioethical imperative to develop such a national strategy.

It is not only bioethics involved, as you know, Dr. Williams, it is also cost effective. The NIH has estimated that up to $300 million a year, most of it in Federal funds, could be saved if we doubled the number of kidneys available for transplantation and equal savings could be found from the transplantation of other organs.

I want to apologize to my colleagues for taking so much time. I will come back for more questions on the second round.

Congresswoman Schneider.

Mrs. **Schneider**. Doctors, I am a very strong advocate of prevention, and I can't help but wonder, since most of our discussions have centered around small children and the diagnosis of the liver diseases coming something like 2 weeks after birth, is there some research, or have we already determined what are the causes of the diseases we have been talking about?

Dr. **Starzl**. In many of the pediatric diseases, genetic counseling might help prevent somebody being born with a genetic taint. The fact of the matter is that something like six or seven of these so-called in-born errors have now been effectively treated with livers, because if the in-born error is a basic enzyme deficiency of the liver or hepatic based in other ways, possibly because of enzymes missing that you don't even know about, the provision of a new liver from a normal person will provide a permanent cure. In other words, if you get my liver and you have got some flaw in yours that is genetically determined, you will always have the function of my liver, and it will make up for what you are missing. But that is curative. If you took the same diseases—there are, I think, seven of them now that have been treated in this way—it might be possible to prevent them.

The most common pediatric disease is biliary atresia. That is not a genetically determined disorder. It is a disease that affects about 1—these figures vary somewhat—but perhaps 1 in 8,000 births. I calculate it out that, in the United States, that means we are producing about 500 new biliary atresias each year. It is those children with biliary atresia who are providing most of these anguished calls that you are getting, or many of them. Because they tend to be very attractive children, they receive an enormous social' economic and medical input and, in the long run, there is no dividend unless something decisive can be done.

But I think that is not a preventable disease. I don't really know what causes it. Although there is a lot of speculation about it, I don't think there is any information on it.

Mrs. **SCHNEIDER**. Is there some kind of research going on now into the cause?

Dr. **STARZL**. I think there is a good deal of research, but there are no leads, to my knowledge.

Just to show you where basic research can sometimes lead, a very bright pediatrician named Harvey Sharp at the University of Minnesota in 1967 discovered that alpha-1-antitrypsin disease had an association with hepatic disease— it was known previously to be associated with pulmonary disease. That one little discovery has opened up an enormous Pandora's box of new information and has made it possible, in some instances, to carry our prophylaxis because alpha-1-antitrypsin disease, as it turns out, is one of the leading causes of neonatal jaundice. That all has only been known since 1967.

Mrs. **SCHNEIDER**. Part of the reason I am asking is because the Science and Technology Committee, of which we are a subcommittee, has responsibility for the budget of many of the basic research programs that are going on, both in the Federal institutions and also in many of the universities.

We have been talking mostly about children and liver transplants. Are there many adults who are in need of liver transplants?

Dr. **STARZL**. Yes, I think that two-thirds of the candidates, excluding the alcoholic population—just the ones that we have been about to treat—have been adults. It is a crippling disorder. Alpha-1-antitrypsin disease pops up in adult life as well. But I won't ever bore you with a list. It is a tedious list of indications or of diseases that are nonalcoholic and cause end-stage liver disease. They affect people of your age, young people who are vital——

Mrs. **SCHNEIDER**. Flattery will get you everywhere.

Dr. **STARZL**. It does affect people in the 20, 30, and 40 age range. Our upper limit for liver transplantation in adults has been pretty much arbitrarily set at 50 to 55.

Mrs. **SCHNEIDER**. And it is possible to transplant the liver to a person who has alcoholic cirrhosis?

Dr. **STARZL**. Yes, without disclosing a name, our longest patient is about a decade with alcoholic liver disease, and this was a pretty well-known professional football player at one time who has never had a drink since that time and has become a major drug abuse and alcohol rehabilitation officer in one of the important States. Also we did a man who became the chief of an Indian tribe. We did him 7 or 8 years ago.

So I don't think that, out of hand, one can exclude for future consideration alcoholics. We already know that the incidence of recidivism is rather small in people, even people in the alcoholic population, providing careful screening is carried out and there is some evidence of abstinence in advance from alcohol.

Mrs. **Schneider**. Do liver transplant patients require life-long monitoring or constant treatment?

Dr. **Starzl**. Yes, but it is a very simple situation. I am glad Danny Butler is here, because we see him about once a year, and I suppose he sees his doctor here about once every couple of months. He really just lives a normal life. The people that get out months or so after transplantation can do well, just like Norm's famous patient who got on a bicycle and rode it from coast to coast. They are not strange. You wouldn't even be able to recognize them if you met them on the street.

Mrs. **Schneider**. You had mentioned in your testimony, Dr. Starzl, that at times it is easier to operate, and one finds operating better in both Europe and the Far East. I wonder if you could elaborate on that.

Dr. **Starzl**. There are a number of centers in those parts of the world. Some of them will make depositions at the Consensus Conference—Rudy Krom in Holland, a group working in Munich, and a group working in France. They all are representatives that at one time trained with us. Then we have trained people in Japan——

Mrs. **Schneider**. But you mentioned that it was sometimes easier to operate in foreign countries. I was wondering if you were implying——

Dr. **Starzl**. No, I just meant that they have had an easier time setting up programs. For example, Italy just made a decision that they were going to set up three transplant programs, one in Milan which is on its way, one in Rome, and the third one in an unspecified city about which they are presently struggling. But it is known there that there are going to be some centers, and they have been set up. They are not research centers, they are service centers. I think that is going on in Italy, in France, in Germany, in England, and so on. England, I think, has now got a second one.

I think we are behind in our regionalization, if you will, in making it feasible to go forward. That is the trouble that Jim Williams has gone through. What he has done has been perfectly extraordinary.

Mrs. **Schneider**. In the Modern Medicine magazine in April a few years ago, you were interviewed and you had said that now you have solved the problems of supply and duct integrity; you are now looking for better immunosuppressive techniques to improve the survival rates of transplant patients. This interview was conducted back in 1976, and I wonder what the timing was for the introduction of cyclosporine?

Dr. **Starzl**. Cyclosporine surfaced with a paper given by Jean Borel, the Sandoz immunologist, in 1976, and was seized upon by a man named Dave White working at Cambridge. An experimental supply became available in 1977 in Europe. Many people around the States knew about it. We did. But you really couldn't get it. It was priceless at first.

Mrs. **Schneider**. Now I understand that the process to manufacture it is a rather cumbersome ordeal. I wonder if you could elaborate on how expensive it might be?

Dr. **Starzl**. I am told by the people in the company it will cost for a patient for a year $5,000 or $6,000, something in that range.

Mrs. SCHNEIDER. For a year.

Dr. STARZL. I am not sure that they would really want me to say anything, and I have nothing to do with the company. This was a question, though, that was asked at the FDA meeting here 2 or 3 weeks ago, and that was the answer that was given in a public forum.

But, as Norm said, it has been synthesized. A man named Wenger synthesized it. It is thought that analogs will be forthcoming. The problem with the synthesis presently is about the same as with penicillin many years ago, in that the synthetic process is cumbersome and takes about 35 steps. I am told that to be commercially feasible, it has to be in five steps or less.

So, at the present time, it is a biologic preparation. It is an extract from some fungi. You have to grow those fungi and then collect the extract, and so forth. I think it is cumbersome, but it almost certain to become simpler as time goes by.

Mrs. SCHNEIDER. Fine.

I would like to personally thank you, Dr. Starzl, for your efforts last night and this morning. The operation that he was involved in was on one of my constituents, and I am very appreciative for your personal involvement and oversight in this case. I am hopeful that very soon she will be in good shape.

I thank all of you for your very informative imput.

Mr. GORE. Congressman Durbin.

Mr. DURBIN. Thank you very much, Mr. Chairman.

I, several years ago, worked with the Illinois State Senate Judiciary Committee, and we put together the Uniform Anatomical Gift Act in the State of Illinois, and tried to set up a procedure through our driver's license, I think, very similar to what you described today, to increase public awareness. I don't know how successful it has been in our State.

After hearing your testimony, I am wondering if all of our efforts in that regard, aside from increasing public consciousness, made it any easier for you as a surgeon looking for a donor to have people available when you need them. Has it worked? Is it still too cumbersome?

Dr. G. MELVILLE WILLIAMS. Yes, it is far too cumbersome.

What, I think, would help would be to have many of the so-called safeguards removed. For example, why is it necessary for an individual to have two witnesses in order to make a statement "yes" or "no" if he wants to donate his body for transplantation?

Mr. DURBIN. I can tell you why, but it still doesn't make any sense.

Dr. G. MELVILLE WILLIAMS. Yes, I know. You see, we make it very, very hard to opt into the system. There is plenty of evidence to state that, given a choice, 2 percent of the people go to the time and trouble of filling out the forms, getting their witness—which might be strangers in the line waiting to apply for their driver's license—I did that once, and everybody thought I was a nut.

Dr. STARZL. It can be done simply. I worked in Colorado for a number of years, about 19 years, and it was no accident that that driver's license law that was described earlier was in Colorado. But that didn't require witnesses. You expressed an opinion as you went through. Now, that probably did not carry the legal weight that the Maryland document does. The Maryland document presumably would allow the doctor to go right forward without any family permission, and I never construed the Colorado document that way.

But what it did do was to create an ambience within the family so that everybody knew that this guy checked that off—almost always yes—and at the last count when I left there, there were about a million of the driver's licenses in Colorado that had been checked off—yes.

Mr. **Durbin**. Does that work, though, States like Colorado?

Dr. **Starzl**. I don't think it works in terms of a point-to-point procurement. But I must say that there were a lot of donors in Colorado. It was a very, very effective donor center, one that was so effective that, for a long time, it was one of the main sources of kidneys for New York City and also for the west coast. It was a very effective center.

But that all is kind of nonspecific. I will bet you anything that they are busier than heck out in San Francisco because, whenever extra-renal organs get into the picture, they attract a lot of attention. It automatically gears up the kidney procurement. It really helps. So these are reinforcing procurement problems, the renal and the extra-renal ones.

Mr. **Durbin**. Many Members of Congress write weekly columns and send them back home about things we do in Washington. I would like to write a column about this testimony today. I would like to end it by making specific recommendations to the people that read it. I am trying to, from your testimony, come down to some very basic things that everybody could do, having heard what is needed and really appreciating what they can do.

I think that the first thing—and Chairman Gore deserves commendation from all of us, because there are plenty of things that we could be talking about and I can't think of anything more important today, and he in his effort has increase public awareness—but as he mentioned earlier, just sitting down with member of your family, and at least have an understanding about what your personal feelings are so that, if there is an accident where your life is threatened or a fatal accident, they will have an idea what decision to make. That sounds like a pretty valid first step.

I guess the second one is—I looked at may own driver's license and, having worked on that law, I never signed the back of it on the donation of organs because I was never asked in line and it never crossed my mind. It seems to me that we ought to be more conscious when we renew our driver's licenses about these provisions in some States, and perhaps contact legislators in some States that don't have this law.

Would the third thing be to contact local medical societies and ask them what kind of organ donor societies are available or associations? I have been contacted at church picnics about donating my organs.

Dr. **Starzl**. I think that is an important thing to do. It is curious that I never really took the necessary effort to do it voluntarily. I was asked to do it by the Journal of Pediatrics. This was involving an interest in which I had a major investment, that is the liver transplantation, because the small donors, as you have heard this morning, are the ones who are in short supply.

At the same time, in a quite formal surgical literature, many papers are now coming out. As you pointed out, Mel left a very important meeting in Holland that was considering some of these questions. Studies were being reported at the meeting about the function of different organs when taken out in conjunction with other organs. That is in the literature, and it is apt to increase the physician awareness.

Just so you know exactly what I am talking about, we heard from Mel that the national incidence of failure of kidneys to function promptly is rather high, 30 to 35 percent, in that range. But in the heart donors, at least in the Eastern half of the United States, that figure is less than 10 percent for malfunctioning kidneys, and in liver-plus-heart-plus-kidney donors, it is the lowest of all, probably in the order of 5 to 10 percent.

What this really means is that the removal of these extra organs does not jeopardize the kidneys at all. As that kind of information gets out, I think it will automatically impact on the physician acceptance and acceptance by the kidney transplant surgeons.

Mr. **Durbin**. What can the average person do to help along in this physician awareness? Is it a waste of time to write a letter to your local medical society and say that I hope you are participating in some sort of education program?

Dr. **Starzl**. I think that is going to have to come from us. We have been negligent. Mel, by virtue of being president of the American Transplant Society--which has an educational arm—should be able to do something. I think that we are going to have to work on that, because we are asking you to do things we are not even doing our own homework on, it looks like.

Dr. G. **Melville Williams**. Doesn't the Emergency Medical Service—isn't that a federally sponsored program?

Mr. **Gore**. They get some assistance, yes.

Dr. G. **Melville Williams**. I remember several years ago trying to drum up interest, stating that within that system there be developed some guidelines for the recognition of donors. As it stands now, I don't believe that that is done. In other words, this is something that is within the boundaries of Federal enterprise.

Mr. **Gore**. We are going to hear a specific recommendation on that from a witness tomorrow, and we anticipate including that in our lengthy list of recommendations when we report at the end of the 3 days of hearings. I think that is an excellent suggestion.

Mr. **Durbin**. Dr. Shumway, could I ask you a question or two here? I am particularly interested in some aspects of your testimony.

Is there a rather free exchange now of information among countries that are interested in transplantation?

Dr. **Shumway**. Yes; there is. I know more, of course, about hearts and lungs, and so forth, than the others, but most of the people who are interested in developing these clinics doing transplant of the extra-renal organs such as heart or heart-lungs are people who have been through our place and who spent time with us. And there is a free exchange of information.

Mr. **Durbin**. Do you feel there is any resistance within the medical profession to the idea of transplantation? I got the impression about 10 years ago in speaking to a heart surgeon that the idea of transplantation was something that was considered too experimental, at least in the heart area. Has that changed remarkably?

Dr. **Shumway**. I think it is changing. I think the good results that are currently possible have pretty much dispelled all of that original doubt, but there are still units, though, that, for one reason or another that are very difficult to understand, are having trouble with the survival statistics—after transplantation of the heart, for example. But this is less and less of a problem. Today, there must be a half a dozen centers in Europe that have good programs in heart transplantation, and probably 12 to 15 such centers in the United States.

Mr. **Durbin**. Can we look to the day in the next 5 or 10 years when heart-lung transplants will be considered at least as common as kidney transplants?

Dr. **Shumway**. I don't think so, no. I don't believe there will ever be the incidence of transplantation of those organs that you see in the kidneys, nor do I think there will be the need. It is possible, but certainly not in the next decade.

Mr. **Durbin**. I am interested in that comment that there wouldn't be the need. Could you expand on that a minute?

Dr. **Shumway**. Yes; for example, in cardiac work, the original conditions that mandated the possibility of transplantation are now being ameliorated by new operations that are being developed, different techniques, even occasionally we might get around to preventive medicine from the standpoint of coronary artery disease. On the horizon, there is the use of the laser to melt away coronary lesions. So, there are all kinds of developments that are, I think, going ahead in that field that would tend to keep the incidence somewhat lower than the kidney.

Mr. **Durbin**. Do you see it as advisable from a national viewpoint that there be more centers in the near future that would consider heart-lung transplantation as at least a procedure that they would have people proficient to perform?

Dr. **Shumway**. Yes; I think so. As Dr. Starzl said, people are being trained in these aspects of transplant and are now moving to other medical centers around the country. So, there will certainly be an increasing number of such cases performed.

Mr. **Durbin**. Does this particular procedure, the heart-lung transplantation, call for a substantial investment in new equipment for a hospital that would want to undertake the program?

Dr. **Shumway**. No; not at all.

As a matter of fact, as I tried to intimate in some of my earlier remarks, the early results from heart-lung transplant patients seem to us to be better than the results from heart transplantation alone. There are many possible reasons for this, and some of them are entirely speculative. But, nonetheless, it is an extremely interesting era that I think will be explored much more fully in the next few years.

Mr. **Durbin**. I want to commend the panel, too. I think you make some very telling points on the economic aspects of this discussion. I do not envy your job for 1 minute. I have been to Houston and saw what Dr. Cooley faces every day with people waiting in the room begging for the chance to be operated upon, and you have to face that day in and day out. That human aspect is something that I think is a burden that many of us don't appreciate until we have been there.

But I would say that, from a governmental viewpoint, we are coming down more and more to a question of it is your money or your life. When it comes to health care and the expenditures of money in light of some of our fiscal problems, I think that the American people are saying quite clearly that they want good health, they want the best medical techniques available, and I believe they are prepared to pay for it.

When we hear what you have said concerning the long-term savings, Dr. Starzl, the long-term savings of this type of approach, it makes our job that much easier to concur with that belief that we have got to have the best health care in this country available to everyone.

Thank you all.

Dr. Shumway. One thing that should be pointed out is that, in the world activity in health care, the United States is absolutely preeminent. It may be falling behind in automobiles and various other technologies, but in health we are way ahead. I think we would certainly like to keep it that way.

Mr. Durbin. You bet. Thank you very much.

Mr. Gore. We certainly would.

Just following up briefly on my colleague's questions, 15 years ago, an NIH task force estimated, Dr. Shumway, 12,000 to 32,000 heart transplants a year.

Dr. Shumway. That was absolutely ridiculous. I don't know how they sat down and arrived at that figure, but it is quite preposterous. That would be a situation perhaps when we would get around to the point when we could use animal donors for transplantation purposes. Those figures are phony.

Mr. Gore. You mentioned the subject of animal donors, the so-called xenografts. You were quoted recently as saying that you believe that ought to be actively studied?

Dr. Shumway. It is, yes.

I think one point—and Dr. Starzl knows more about this because of the renal xenografts that were used in Colorado in the early days—but in New Orleans, for example, one chimpanzee kidney survived for 10 months in a human recipient. What we are talking about today in terms of homografting or allografting may be, in the long view of the subject, just a step toward the availability of other kinds of donors, namely xenografts. But there is quite a bit of work going on in this area now.

Mr. Gore. In other words, partly because of the shortage of human donors, you are actively exploring the possibility of transplanting animal hearts into patients.

Dr. Shumway. Yes, but it is still in the distant future. I wouldn't want anybody to think that this is just around the corner. This is really a developing area of research, even now.

Mr. Gore. I see.

Dr. Starzl. Also, there has been some understanding about the nature of the animal donors that is a little bit disquieting since those early days. I have had experience with baboon and chimpanzee heterografts, what you are calling xenografts. The baboon, I think, is too far away from the human, although those kidneys did function for about 2 months or maybe even a little longer than that. But the rejection was very hard.

I think what Norm may be driving at is that there has been a lot of awfully good information coming out about the effect of cyclosporine in heterografts. It, of course, has improved the outlook there as well.

But I was reminded that we, in a very serious emergency situation at one time, did a chimpanzee heterograft to a child whose first human liver had failed, so we were really against the wall. We got from the Air Force a chimpanzee that was 3 or 4 years old, and the chimpanzee was brought to Denver in a cage and was brought over to my house and had tea. It actually was able to have tea. When it finished it made some human gestures, and so forth. It was so human, it was uncanny. I was really uneasy about taking that little chimpanzee's liver. I would never do it again. It is too close to being human.

I saw a program not long ago on television about the origin of man, and it made it pretty clear that the gestures and the facial expressions and the powers of reasoning that chimps have are so close to human. I would have a lot of trouble doing that again. But, to me, that is the only animal right now that is close enough to the human to hold a lot of promise of immediate application. It is probably a sentimental point of view anyway.

Mr. GORE. Just briefly, how do artificial organs play into this problem? Is it safe for me to assume that the future utility of an artificial heart is problematic, and the number of patients who will benefit is probably sharply limited; and second, that it is highly unlikely that we will see artificial kidneys or livers or pancreases or lungs at any time in the foreseeable future?

Dr. SHUMWAY. I think that is true. I think the recent experience in Utah lasted much longer than anybody had anticipated. Certainly, the kind of apparatus that is available now and was used there is in no way similar to what you would expect the final artificial heart development to be like. So, I personally, believe we will be using xenografted tissue before we have the inexhaustible totally implantable nonheat-producing kind of power source. It will probably be in our automobiles and refrigerators first, before artificial hearts.

Mr. GORE. Congressman Reid, did you have any questions?

Mr. REID. No, I don't, Mr. Chairman. Thank you.

Mr. GORE. Congresswoman Schneider?

Mrs. SCHNEIDER. I just wanted to follow up on some of the questioning a little earlier on cyclosporine. Where does it sit right now with the Food and Drug Administration?

Dr. STARZL. They had a meeting over there on the 25, and they asked me to give data for it because we had one of the studies. The advisory board voted unanimously to move to whatever the next step to general release is, to go forward with that. I don't really know what the pathway is from that point onward, but certainly it passed through that the first steps quickly.

Mrs. Schneider. Is there any reason that you presented or others presented to the Food and Drug Administration as to why it shouldn't be used?

Dr. Starzl. No; it was uniformly favorable testimony, I would say.

Mrs. Schneider. OK. Thank you very much.

Mr. Gore. How close are we to offering any sort of hope to the 1.5 million diabetics who I am told would benefit from a pancreatic transplantation procedure, Dr. Williams?

Dr. G. Melville Williams. I think this will probably be the next organ to surface in a dramatic way in transplantation.

The problem with diabetes is that it is really quite different in nature than the other diseases that we are talking about where failure is equivalent to death. The pancreas can fail and a patient can be sustained on insulin for a long period of time. So, the point at which one intercedes is a point way down the line somewhere after the complications have already developed.

So, this has, been one of the problems. Most of the diabetics who have been transplanted so far have had concomitant kidney failure.

Mr. Gore. I see.

Dr. G. Melville Williams. When and if the results become well known and if they continue to improve as they are, then it would give us justification to intercede at an earlier time period. I think it will, in the next 3 or 4 years, be a very important organ to transplant.

Mr. Gore. Dr. Starzl?

Dr. Starzl. Probably the time is here now. We have done two pancreas transplants over there in Pittsburgh. We didn't do it for a long time because we were not satisfied that the technical aspects of that operation had been worked out. But I am satisfied that that is the case now. I think that we will go forward at a steady, although not a panicky rate, with the pancreas.

There are a number of centers around the country that are all doing good work. Minnesota has done more than any other center. The University of Cincinnati is a good one. Some of the surveys from these regional procurement groups—yours, for example—showed quite a surprising number of pancreases being done.

I think the biggest deterrent to going forward with pancreas transplants is the very one that Mel described, and that is that there is a very sound alternative form of therapy. But in some patients, it doesn't work. Some people die from diabetes mellitus. On the way to dying, they usually develop multiple organ failure, including the kidney. So, perhaps it is appropriate—you sounded as if you thought maybe that was being too restrictive—but I think it may be appropriate to not even consider a pancreas until you have bone fide evidence of failure of the second organ system, and that would usually be the kidney or the eyes, impending blindness.

Do you want to comment on that?

Dr. G. Melville Williams. Yes; that is currently, I think, the accepted way. But I suspect that, when the results get better, the demand will be made to transplant somebody with a creatinine of 2.2, as opposed to transplanting him when he is on dialysis.

Dr. **Starzl**. Then, there is really going to be a horrible crunch, but I don't even want to think about that. I think that, in many ways, the transplantation of the pancreas and the liver are, although they are said to be compatible, basically incompatible procedures using the same donor.

Mr. **Gore**. We are talking then in descending order of how common they are, the kidney transplants, liver transplants, heart transplants, heart-lung transplants and pancreas transplants. The only other item on the agenda would be corneas; is that right?

Dr. **Starzl**. No; the intestine is coming up also.

Mr. **Gore**. The intestine is coming up also.

Dr. **Starzl**. Yes, sir, it had never been possible, although many people tried over two decades, to obtain chronic survival in dogs after intestinal transplantation. Suddenly, it became possible. A group up in London Ontario did it and we did it. We have two dogs that are 600 or 700 days after complete midgut, complete intestinal, transplantation. They look completely normal. So, I think that is another area that will be explored.

Here, I think that, at least until it really gets worked out, I would call that an experimental procedure.

Mr. **Gore**. I see. And then, of course, bone marrow transplants are in a slightly different category because it is renewable?

Dr. **Starzl**. Yes; that is no longer experimental. That is a spectacular story of its own.

Mr. **Gore**. Yes.

How are the two pancreas transplants doing?

Dr. **Starzl**. They are doing fine. They are former diabetics.

Mr. **Gore**. Let me thank you again for coming and for honoring us with your presence. You gentlemen are heroes in America for the lives you save, for the work you do, and we can't thank you enough for taking time out of your very important activities to share with us in an effort to try to develop a national strategy for what is surely going to be a dramatic upsurge in the need to obtain organs and to deal with the surrounding problems in a more rational and effective way. Thank you very much.

Dr. **Starzl**. Thank you.

Mr. **Gore**. Our final panel today is made up of Mr. Donald W. Denny, director of organ procurement, Transplantation Office in the University of Pittsburgh School of Medicine in Pittsburgh; Raymond Coleman, founding president of Donor Alert, Warwick, R.I.; and William W. Pfaff, M.D., past president of South-East Organ Procurement Foundation at the University of Florida College of Medicine in Gainesville, Fla.

We will begin with you, Donald W. Denny, director of organ procurement, Transplantation Office, University of Pittsburgh School of Medicine. Welcome.

Without objection, your entire text will be included in the record, and we invite you to proceed with your presentation.

STATEMENTS OF DONALD W. DENNY, DIRECTOR OF ORGAN PROCUREMENT, TRANSPLANTATION OFFICE, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE, PITTSBURGH, PA.; WILLIAM W. PFAFF, M.D., PAST PRESIDENT, SOUTH-EAST ORGAN PROCUREMENT FOUNDATION, UNIVERSITY OF FLORIDA COLLEGE OF MEDICINE, DEPARTMENT OF SURGERY, GAINESVILLE, FLA.; AND RAYMOND COLEMAN, FOUNDING PRESIDENT, DONOR ALERT, WARWICK, R.I.

Mr. **Denny**. Mr. Chairman, members of the subcommittee, I thank you for conducting these hearings today. The subject of organ procurement and distribution for transplantation is of national concern.

Despite the headlines that you perhaps have seen, and despite some of the comments that I have heard here today, I would like to indicate at the outset that I believe there is in effect today in this country an effective system for the procurement of vital organs for transplantation. It is not a random process.

The process is not an easy one. The system is not a perfect one. We have heard that there are this year approximately 2,500 postmortem organ donors, but yet all studies indicate that this is anywhere from one-tenth to one-third of the potential donors from whom organs could be recovered.

The recovery of organs for transplantation is a three-tier process. In trying to understand where the problems lie behind the shortage of organs, behind the fact that we are now recovering so few of the organs from all of the potential donors, I would like very briefly to outline this three-tier process. The three tiers are, in short, the organ procurement programs in this Nation; the physicians and nurses at the acute care hospitals in the United States; and third, all of us, the general public, those of us who inevitably will die, those of us who will succumb at one time or another, and who could be potential vital organ donors.

The first tier, the organ procurement programs in this country: There is a nationwide regionalized system for the recovery of organs for transplantation. There are in the United States approximately 110 organ procurement programs. These 110 programs have been established over the past several years primarily to serve the need for the recovery of kidneys for transplantation. In recent years with the development of extra-renal—that is, organs other than kidneys—transplantation, these 110 organ procurement programs have been challenged to recover hearts, livers, heart-lungs, pancreas, and so forth, as well as kidneys from their donors.

The 110 organ procurement programs in this country today are, in large part, run by and made effective by the organ procurement professionals, nonphysicians like myself, most of whom belong to a nationwide association of coordinators, the North American Transplant Coordinators Organization. Over 360 of us in this country labor to provide organ donation education of physicians and nurses, as well as the public. We are also available generally to receive the referrals of donors, to evaluate donors, and to assist on the scene in donor hospitals in making possible the necessary clinical, medicolegal, and psychological adjustments which are necessary to recover the organs for transplantation.

The 110 organ procurement programs and their associated organ procurement coordinators struggle to provide professional education, to doctors and nurses especially. In my area, I speak over 120 times a year to medical staffs in acute care hospitals, to critical care nurses in intensive care units and emergency rooms, trying to help them understand the importance of recovering organs for transplantation, conveying to them who donors are, helping them understand how to manage these donors so that vital organ function can be sustained, helping them understand the psychology of the donation process in dealing with grieving families.

But it is not just a matter of information giving, unfortunately. We are all besieged by sources of information. We are all besieged by demands to pay attention to urgent needs. Maybe this is especially true of physicians and nurses.

Information giving is frequently not enough—helping a doctor understand that there is a need for organs, who donors may be and what the process is. Sometimes the challenge is to excite them, to make them feel it as we feel it. And sometimes we despair because we are unable, through information giving or through challenging their feelings of caring for dying patients, we are unable to secure their cooperation.

The dissemination of information to physicians and nurses carried out by the 110 organ procurement programs in this country has been spotty in some areas. We have received referrals of donors and calls from physicians as far away as the west coast who have called Pittsburgh to ask who donors are, what should they do because they think they have a donor in the hospital, and they are unaware of their own local organ procurement programs. I don't mean to fault the organ procurement programs in these other areas of the country. It is a tremendous job to try to educate and sustain interest among physicians and nurses in organ donation when their primary concern is caring for living patients, patients who are ill of other diseases.

Because of the apparent lack of a uniform method to educate physicians and nurses in this country today, because of the apparent holes in our educational system, the North American Transplant Coordinators Organization recently established a 24-hour information and referral service for doctors and nurses throughout the country. An 800 number, so it is a toll-free call, is available to physicians and nurses anywhere in the Nation who are not aware of who donors may be or who do not know how to contact their own local procurement program. This 800 number is a mnemonic number that is easy to remember, 800-24-DONOR. You pick up the phone and dial 800-24-DONOR.

Mr. GORE. How recently was this established?

Mr. DENNY. This was established 10 days ago.

Our struggle now is to acquaint physicians and nurses throughout the country with the availability of this number. Let me stress that this 800 number is not meant to supplant the 24-hour referral numbers in place at the 110 organ procurement programs. Instead, this 800 number is meant to supplement it, to provide information for a doctor who does not who to call in his own area and, believe me, there are many of them.

The organ procurement programs, going further into my brief look at this three-tier process, also, in addition to providing education, provide the manpower and the technology for the recovery of organs for transplantation. Surgeons, physicians, and paraprofessionals like myself are available 24 hours a day, around the clock, throughout this country, to recover vital organs for transplantation. We don't lack the skill, we don't lack the manpower, we don't lack the technology to recover organs for transplant. Every organ procurement program has as one of its major goals the recovery of kidneys for transplantation for the nearly 6,000 people who are now waiting for renal transplantation in this country.

Additionally, however, the organ procurement programs collaborate to a great degree in the recovery of extra-renal, nonkidney, organs for transplantation. Cooperation between these 110 organ procurement programs has developed dramatically over the past 2 years. Witness the fact that the University of Pittsburgh, which has a very large waiting list for liver and heart transplant patients, now works collaboratively with other organ procurement programs around the country in recovering two-thirds of the livers that we transplant and three-fourths of the hearts that we transplant. In other words, our own area, within 140 miles of Pittsburgh, which is the geographic region that our organ procurement programs covers directly, isn't sufficient to provide the organs for transplantation that we need, especially in the area of livers and hearts.

Through the collaboration of other organ procurement programs, we have flown as far west as Oklahoma City and Fargo, N. Dak., and as far south as Houston and Miami to recover organs for transplantation through the good efforts of organ procurement professionals in those area.

Yet, I have to admit before this committee this morning that, although we have collaborated with almost 50 of the 110 organ procurement programs in this Nation recovering extra-renal organs, there are still many of these programs that do not call us when they have kidney donors, and do not give us an opportunity to recover livers or hearts from their donors.

The system is developing. One of the reasons that we don't receive collaboration from all of the organ procurement programs is that they are in need also of education. They need also to understand that working with us in recovering hearts and livers is not going to compromise their kidneys which they need desperately for transplantation locally.

In addition to organ procurement education, and procurement services, organ procurement programs are actively involved in the distribution of organs for transplantation. In the case of kidneys—you shall hear from Dr. Pfaff in a few minutes—there is a computer system which is an excellent means of locating suitable recipients nationwide for transplantation of kidneys. When we have kidneys available in the Pittsburgh area that we are unable to transplant among our patients, the computer will print out for us a list of suitably matched recipients throughout the country.

The computer system has limtitations, however. In the distribution of extra-renal organs, a somewhat different system has been utilized to supplement it. The computer is a fixed-base operation. A terminal is located in my office, but there is no terminal in the community hospital where I may have a donor. What do I do at 2 o'clock in the morning when a donor is identified in a community hospital 100 miles from Pittsburgh and I am preparing to sit down and talk with the grieving family to suggest that they donate organs? I need to know immediately where a suitable recipient for the heart or liver may be. In the case of kidneys, we can wait until the organs have been removed and access the terminal when we get back after the donor surgery. In the case of hearts and livers, we need to know where the recipients are before we remove the organs because of the very limited preservation times that we have for these organs.

I can't access a terminal at 2 o'clock in the morning from 100 miles away from my office. Instead, what we have now is a 24-hour telephone system, also established by the North American Transplant Coordinators Organization, a telephone system which is contrived to provide information concerning the needs for hearts, livers, heart-lungs, and other extra-renal organs to organ procurement professionals around the country. Twenty-four hours a day, if we access a central telephone number, we are informed through a recorded message of what organs are needed from Stanford, Calif., to Pittsburgh, from New York City to Virginia to Memphis, Tenn.

Fifteen extra-renal transplant centers now cooperate and list their extra-renal organ donor needs on this 24-Alert System. The calling coordinator or physician will be told the blood type, the size of the donor that is sought, the distance that the transplant center is willing to fly, the telephone number to call if a donor is available. The caller is also informed of the potential recipient's medical condition, that is, the degree of urgency for transplantation.

Brandon Hall today is flying back to Memphis for his liver transplant. This liver transplant was made possible by the fact that the organ procurement coordinator in Virginia who recognized the donor called the 24-Alert telephone number and was informed through this service that the University of Tennessee, had an urgent need for a pediatric donor liver of a given size and blood type for Brandon Hall. He copied down the phone number and gave them a call.

This system doesn't sound very sophisticated. Computers sound so much more high-tech, don't they, than phones and recorded answering services? But this system works. It is effective. It is available to all of us, and it has made possible in the last 6 months the transplantation of 48 livers at 5 centers, and 25 hearts at 9 centers.

Going on briefly in my description of the three-tier system, the second tier are the health professionals, the doctors and the nurses in this country, who are in a position to recognize suitable donors to provide the organs for transplantation.

I have been an organ procurement professional for the past 9 years. I am glad to say that the physicians and nurses in this country, by and large, support organ donation. Unfortunately, however, verbal support isn't sufficient. We also have to have their active support. Unfortunately also, it is accurate to say that many physicians and nurses do not collaborate with us in recovering organs for transplantation.

Ignorance, apathy, indifference, they all play a part. But perhaps the biggest problem is the medicolegal problem—physicians and nurses who fear that if they cooperate in the recovery of organs for transplantation, they will be vulnerable to litigation. We live in a litigious society, and physicians especially know how damaging nuisance lawsuits can be. As a result, they oftentimes practice defensively. Their patients are not waiting for transplants, and our requests that they help us sometimes fall on deaf ears because of their fear of medicolegal vulnerability.

Brain death is a central issue related to organ donation. You can't escape it. By definition, all donors are victims of brain death. They are medically and legally dead because their brains are dead. They are no longer thinking, feeling, willing, reflexive people. Artificially their hearts and their respiratory systems continue to function, and this is what allows the viability of the organs to be preserved until they are removed and chilled.

Physicians are especially concerned about the public's acceptance of brain death. Thirty-five States now have passed statutes recognizing that brain death is death. Fifteen States do not have laws defining brain death, but in those 15 States, common law or apellate court decisions allow the recovery of organs for transplantation following pronouncement of death on the basis of brain death.

But despite legal support, doctors and nurses often fear that the public does not accept brain death and do not cooperate with us. Less than 1 percent of all the deaths that occur in this country occur under the circumstances of brain death and among the population that is within the right age frame to be a donor.

In my mind, the health professionals, the doctors, and the nurses in this country, are the weak link between the first tier, the organ procurement programs, and the third tier, the lay public. In my experience in the Pittsburgh area and in Pennsylvania generally, approximately one out of five families says no to organ donation; but four out of five families who are approached and offered the opportunity, say yes. These figures are not duplicated in many other areas of the country, however. As you have heard today, cultural, racial, and educational factors influence whether or not members of the public will say yes to organ donation at the time of death.

The American public, however, does have a big heart. One of the gratifying aspects of my job is that I deal with these grieving families and see firsthand the value that it provides the grieving family to be told that the organs from their loved one now sustain life in two, three, four, or five other patients.

In my experience, only 1 out of 10 families of a brain dead victim initiates the request to donate. Most families at the time of death are too overcome with their own grief to remember the need for organs. I am not concerned by the fact that the national Kidney Foundation poll recently found that only 40 percent of the white population and 20 percent of the black population would be willing to donate organs of their loved ones at the time of death. We don't want to believe that we are going to die. We don't want to believe that our loved ones are going to die. As a result, when we are asked—not at the time of death, but at the time of life—whether or not we would donate, of course, we say no. It is too scary to even consider that these people might die. At the time of death, as I said, only 1 out of 10 families initiates the request to donate. But 8 of those 10 families, in my experience, do donate if they are offered the opportunity.

The problem comes, again, at the medical professional level, the need for physicians and nurses to adequately explain brain death to the families and to offer donation. It is so difficult sometimes for doctors and nurses who, themselves, grieve when they lose a patient to sit down and try to explain to a family that their loved one in the intensive care unit is dead. It is especially difficult because this patient does not look dead. He is, remember, a victim of brain death. Artificially, his heart and his lungs are continuing to function.

To try to explain to a family that this brain-dead victim who looks as though he is alive and merely comatose is really dead is a difficult for a physicians, and sometimes they shirk it. Sometimes they shirk it because of their own grief, their own pain, the assault on their integrity which they are experiencing because of the death. Sometimes it is so much easier for a physician to distance himself from the family.

The American public is hungry for information about organ donation. Thousands and thousands of donor cards are distributed by our program and other programs around the country, but it is not enough. We need more public education, not only with regard to organ donation, but with regard to brain death as well. It is time that we stopped hiding brain death and talked about it openly. It is time the medical profession talked about it openly.

Public education in the past has been primarily aimed at the people who already are convinced that organ donation is a good thing. Public education is largely directed toward white middle-class America. We need public educational efforts which are directed toward population subgroups, Spanish Americans, black Americans, Americans from the Mediterranean Basin, and so on. These groups do not donate with the same high frequency as the white middle-class public does.

Physicians and nurses are consumers of the media, and they generally follow and do not lead public opinion. If we educate the public, we will also indeed be educating the medical professionals. If they feel that the public is comfortable with brain death and with organ donation, they will be much more likely to collaborate with us.

I have five recommendations. First of all, it is time that the transplant professionals in this country recognize that they can't do the job alone. There is a need for a national task force to be composed of leaders from government, medicine, organ procurement, and interested lay groups to tackle the problems impeding the recovery of organs for transplantation. It is time that the transplant professionals in this country recognize that they need to involve their colleagues in the medical profession. The neurosurgeons, the neurologists, the critical care medicine physicians, the emergency physicians, the pediatricians should be members of such a task force. They are the physicians who will recognize donors. They are the people who need to be convinced that it is important to work with us.

The critical care nurses are by far our most vital ally. They, too, should be involved in a national task force. This task force should be given the charge of coming up with solutions for developing and improving the system nationwide.

My second recommendation derives from the fact that every hospital in this country must be certified to function, must be certified on several levels. Departments of health in the various States have the responsibility of certifying hospitals in their States. The Joint Commission for the Accreditation of Hospitals also provides accreditation of hospitals on a national level.

There should be developed for accreditation two requirements either on the State or on the national level. The first requirement should be that there be a policy and an operational protocol for the determination of brain death. Second, there should be a requirement for certification that every hospital establish a policy and a protocol for recognizing potential donors and referring donors for the nearest organ procurement program.

Doctors refer donors. Hospitals don't refer donors, but if the hospitals have the rules and the regulations, the doctors may be made more willing to comply, to cooperate.

My third recommendation: there should be a financial incentive program established by the Health Care Finance Administration, which has the responsibility of funding kidney transplantation. A financial incentive would reward hospitals at which donors are identified and from whom organs are recovered.

It is well known that kidney transplantation is much more cost effective than is hemodialysis or peritoneal dialysis for the treatment of end-stage renal failure patients.

This country, and you and I as taxpayers, have an incentive in seeing more people transplanted, if only because it costs less. It makes good sense to me to recommend that the Health Care Finance Administration provide a financial incentive to those hospitals from which kidneys are recovered.

Since almost every postmortem kidney donor is also a potential postmortem extra-renal donor, this will increase the number of extra-renal organs available.

My fourth recommendation is that there is a need for strengthening public and professional education. Public education has been tried in many forms on the local level, for example, health fairs, talks to school groups. These kinds of local educational efforts, to my mind, are not effective.

What is effective is use of the national media, not only to provide information about donation and brain death, but to excite people. We have to inform, but we have to motivate, as well. We have to touch their feelings.

There is much more work that we could do in public education. I would like to see the American Advertising Council take on a campaign in this country to help educate Americans about organ donation.

Finally, there is a need for statistical information. As we have heard today, we have to talk in general figures, because nobody really knows how many potential donors there are in this country, for instance.

Nobody really knows how many potential donors are referred. Nobody really knows how many end-stage renal disease patients there are in this country.

Nobody really knows how many potential recipients of extrarenal organs there are. One vital question, I think, needs to be addressed, and that is how many potential pediatric donors are there between the ages of 6 months and 5 years?

The need for pediatric liver donors between six months and five is tremendous. We have a waiting list of over 35 children in this age bracket who are waiting for liver transplants.

I know, we all know that many of them will die because we will not find organs for them. We may be faced with the fact that there are not enough potential pediatric donors in the Nation to meet the needs of all of these youngsters.

Again, let me congratulate this subcommittee, Chairman Gore, members of the subcommittee, for your interest, for your efforts in spotlighting the accomplishments and the problems and the goals that we strive for as the future unfolds for us in what is a very promising time for transplantation. Thank you.

[The prepared statement of Mr. Donald W. Denny follows:]

TESTIMONY ON
ORGAN PROCUREMENT AND DISTRIBUTION FOR TRANSPLANTATION

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

APRIL 13, 1983

DONALD W. DENNY
DIRECTOR OF ORGAN PROCUREMENT
TRANSPLANT FOUNDATION
UNIVERSITY OF PITTSBURGH

Testimony of DONALD W. DENNY
Hearings on Organ Procurement and Distribution
Investigations and Oversight Subcommittee
Committee on Science and Technology
U.S. House of Representatives
April 13, 1983

My name is Donald W. Denny. I am the Director of Organ Procurement for the Transplant Foundation at the University of Pittsburgh. I am also a member of the North American Transplant Coordinators Organization (NATCO), a professional association of transplant and organ procurement coordinators from the United States, Canada and several foreign countries. My testimony today will primarily reflect my personal experience, attitudes and values. I am also designated as the official representative of NATCO at these hearings, but when expressing the point of view of this association of over 350 transplant professionals, the context of my remarks will identify my position as a spokesman.

I wish to express my appreciation to the Chairman and members of this Subcommittee for conducting these hearings into the subject of post mortem vital organ procurement and distribution for transplantation. I have been closely involved in organ procurement for the past nine years, have participated in the organization of and have administered two organ procurement programs. I believe that the subject of these hearings is a health care crisis, which requires broad national attention and the problem-solving efforts of individuals, organizations and government.

Recent advances in transplantation surgery and immunology now provide the opportunity for additional years of life and health to many Americans who in the past were doomed to an existence supported by a machine, as in the case of victims of end-stage kidney disease, or were cut down by death prematurely, as in the case of people suffering from end-stage heart and liver disease. Other witnesses before this Subcommittee will provide substantive information to support my contention that medical

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science has moved beyond the frontier in organ transplantation, has, indeed, reached a fertile high ground and needs but the active support and investment of this nation to establish a living monument to the value of human life and the spirit of brotherhood: the giving of life, one to another, on a large scale through organ transplantation. My focus today will be with one obstacle impeding realization of this bright promise: the shortage of human organs for transplantation that exists now and, unless nationwide efforts are undertaken, will increase tomorrow.

The shortage of organs for transplantation is not a new problem. My colleagues and I have worked for years to overcome the fact that the demand for post mortem kidneys has long exceeded the supply. The number of post mortem kidneys transplanted in the United States has remained relatively stable for several years, despite the fact that the national waiting list has continued to grow annually. The shortage of kidneys for transplantation has received relatively little attention, largely because renal transplantation is not a form of transplant therapy which is often an alternative to death. We have, fortunately, the artificial kidney machine which can sustain life for most end-stage renal disease (ESRD) patients who elect to wait for a transplant, as well as those patients who do not wish to consider or are unsuitable for transplantation. The undeniable facts that a real kidney, a transplanted kidney, provides a better quality of life for ESRD patients and that renal transplantation is more cost-effective per patient life-year than the artificial kidney have not been sufficient

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to cause the national sense of urgency which underlies these hearings. Without intending to diminish the meaning and the importance of this Subcommittee's purpose today, I must lament, however, the fact that recent publicity concerning the need for a liver transplant for a handful of patients at two or three transplant centers (including my own) has outweighed the silent suffering of many thousands of patients waiting for a kidney transplant at 150 transplant hospitals over the past decade in moving the conscience of this nation.

Yet, it is undeniable that liver and heart transplant candidates, unlike kidney transplant patients, have only one other option: death. I cannot blame the media or the public for being more profoundly stirred by a picture of one sad-eyed dying child waiting and hoping for a liver donor than by cold statistics which represent the plight of faceless thousands of ESRD patients. We who spend our professional lives seeking donors of extrarenal organs (i.e., organs other than kidneys) have also been vulnerable to the poignancy of the individual child's desperate need. And when such a patient dies because an organ is not found in time, we also feel a crushing sense of sadness and failure. But we also feel something else, something the public generally does not, namely frustration and anger. The reason is that we know that many more organs are needlessly wasted than are recovered for transplantation. We know that the shortage of organs at this time is not due to a lack of technology, manpower, knowledge or funding, as much as it is due to ignorance, inertia, selfishness and parochialism.

We know, in short, that despite what one reads in the newspaper, there is a system in place in this country for the recovery of organs for transplantation, but that this system does not work as effectively as possible because of the lack of individual and institutional committment to the recovery of organs for transplantation.

From February, 1981, through February, 1983, 126 post mortem livers were transplanted at the University Health Center of Pittsburgh. During this same period, 44 adults and 27 children died before we found a suitable organ for them. During this same interval, 41 patients received heart transplants at our Center, but 8 other patients succumbed to heart failure before we could transplant them. The success of liver and heart transplantation today is encouraging many more institutions to establish programs for the transplantation of these organs in order to meet the needs of increasing numbers of potential recipients. The problem promises to become worse.

I need to define some limitations in order to express fully the nature of the problem. The post mortem recovery of vital organs for transplantation is limited by the circumstances of death, donor age, donor medical history, quality of organ function and temporal restrictions. Because vital organs are very vulnerable to lack of oxygenated blood at normal body temperature, we are unable to consider as donors of vital organs any individual whose death is determined by the traditional criteria, i.e., irreversible cessation of heart and lung functions. Organ death occurs within minutes of cessation of the circulation. Vital organ

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procurement is limited to patients who are medically and legally dead, but whose heart and lung functions are artificially maintained with mechanical ventilation and intravenous hydration until the organs are surgically removed and chilled. In practice this means that organ donors must be victims of brain death, i.e., patients who have suffered catastrophic, irreversible and complete cessation of integrated brain function as the result of trauma, stroke, brain tumor and/or oxygen deprivation. The brain death syndrome by definition always includes destruction of brain stem function, among the sequelae of which is the total inability to breath spontaneously. Forty years ago before the development of the mechanical ventilator, which is used to take over respiratory functions for patients who have difficulty breathing or cannot breath spontaneously, death of the brain resulted in cessation of breathing and, secondarily, heart failure when the heart muscle died due to lack of oxygen. Use of the mechanical ventilator has intruded upon this natural sequence of events and physicians have had to develop new operational criteria for determining when death has occurred in patients suffering from total and irreparable brain destruction. Pronouncement of death after determination of brain death is a commonplace event in the United States and is sanctioned by either statute or common law in all 50 states. Organ donation is not the primary or even secondary rationale for accepting brain death as death of the individual, but it is a necessary precondition for organ retrieval for transplantation.

Another limitation to donation is donor age. The inevitable consequences of aging, including vascular disease and the slow loss of optimum organ function, limits chronological age acceptable for donors. Kidneys are generally accepted from donors up to their mid-50's and sometime beyond. Liver donors are rarely considered beyond age 45; while heart donors are carefully evaluated if they are 35 and are seldom accepted beyond 40. Minimum age limits are also a factor. Kidney donors must generally be one year or older. Liver donors can be accepted from age 6 months and up, however. Heart donors are seldom less than age 15.

Other factors which can contraindicate organ donation include: previous disease involving the organ considered for donation, infection, cancer (except primary brain tumors) and acute injury to the organs due to trauma, oxygen deprivation and persistent periods of low blood pressure.

How many patients in this country's hospitals are victims of brain death and have suitable organs for transplantation? Again, no one really knows. Retrospective studies of hospital charts of patients dying in hospitals suggest between 0.77% and 3.5% of hospitalized patients are acceptable as kidney donors (1, 2, 3). The difference in the conclusions is due to variations in acceptable criteria between investigators. (The percentage of potential donors in these studies which actually did provide organs for transplantation ranged from 17.0% to 19.03% (2, 3).

Since only patients who die in hospitals may be considered for vital organ donation, it is important to consider that only 38% to 60% of the deaths in this country occur in hospitals

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(1, 2, 3). Assuming that half of the annual deaths in the United States occur in hospitals (which may be generous, since statistics on hospital deaths include patients who are dead on arrival and who expire in the Emergency Department soon after arrival), how many in-hospital deaths occur? In 1981, the last year for which statistics are available, there were a total of 1,987,512 deaths in this country (4), of which 50% is 993,756. Multiplying this figure by the above cited percentages of in-hospital deaths which would have been acceptable kidney donors, yields an estimated range of potential donors in the United States of 7,652 to 34,781. Because the age criteria for liver and heart donors is less liberal than for kidney donors, the potential number of extrarenal donors is undoubtedly fewer than is indicated by this range.

How many donors annually yield vital organs for transplantation in the United States? One way of determining an approximation is by looking at the number of post mortem kidney transplants yearly. In 1981, the last year for which I have firm figures, there were 3,427 post mortem kidneys transplanted in this country. Since each donor yields two kidneys, dividing this number by two results in a figure of 1,713 donors. However, since there is approximately 25% wastage of donor kidneys (as a result of surgical error, unexpected anomalies, no suitably matched recipients available), the total number of available kidneys during 1981 was approximately 4,283, of which one-half or 2,141, represents the approximate number of donors in that year. In other words, we are now recovering organs, at best, from fewer than one out of every three possible donors.

This figure does not represent the total number of potential donors referred to organ procurement programs. Organ donation is a voluntary activity in this country requiring consent of the nearest next-of-kin (a practical necessity for all organ procurement programs even when a donor has signed a donor card or other document allowing recovery of organs after death). Organ donation is unacceptable to some families and a percentage of prospective donors is lost for this reason. My experience is that approximately one out of five prospective donors referred to us does not yield organs for want of family consent. This figure varies around the country according to cultural, racial and educational characteristics of the population. Black families, for instance, are much less likely to donate than white families for reasons which are not understood. The number of families which elect not to donate is, however, somewhat larger, since an unknown number of potential donors are recognized by physicians, who approach the families and are refused, and never inform the local organ procurement program of their efforts.

I value the fact that organ donation in this country is a voluntary, altruistic act determined by the values of the people concerned. National polls have indicated, however, that 70% and more of the people in this country regard organ donation favorably and would be willing to donate a family member's organs at the time of death (5, 6). I would be against legislation which would make donation either compulsory or subject to financial reward. Another option exists, one which is in practice in a few European countries, which is to assume that consent of the individual has been given for post mortem organ donation at the time of his death unless a document signed by the individual indicating opposition to donation is presented when he expires. Given the litigious climate of this country and the vulnerablility of the medical profession in particular to nuisance suits, I doubt that this option is realistic. Even if such a system were legal, I am sure that surviving next-of-kin would also be asked to consent to recovery of the organs, even as they are now.

Obviously, one means of increasing the numbers of organs donated would be to enhance the willingness of families to donate through educational programs. Educational efforts directed at the lay public have been an important component of many organ procurement programs' efforts for the past decade. Many approaches have been tried: professional advertising techniques (billboards, radio and television public service announcements, ads in newspapers and magazines), didactic presentations to students, churches and service clubs and news and feature stories released to the print and electronics media. While I am sure that these efforts have had an impact (some more than others), I am unaware of any reliable studies which can document the effectiveness of public education efforts tried thus far. I am personally biased in favor of the effectiveness of the free educational opportunities afforded by the media, although I have tried all the options cited above at one time or another. News and feature stories focusing on people with whom the public can identify reach the largest audience, have more emotional impact and require less financial investment than costly billboards, public service announcements, health fairs in shopping centers or classroom talks. Stories about patients waiting for transplantation, about patients who have been successfully transplanted, about individual donors and their families' feelings regarding donation have great human appeal. The media becomes quickly jaded, however, and one must constantly seek new "angles" with which to interest the press.

Until recently, kidney donation and transplantation have been the primary thrust of public education for most procurement programs. One indication of the effectiveness of these efforts is the greater frequency with which the public is willing to donate kidneys as opposed to livers and hearts. The heart, of course, is a special case in view of the great symbolic and emotional investment traditionally associated with this simplest of all the vital organs. On the other hand, very little emotional attachment to the liver exists for most of us, and yet many families who are very willing to donate their family member's kidneys balk at donating the liver. The reason, I believe, is that liver donation and transplantation are not yet as well known and accepted as kidney transplantation.

Most public education efforts in some way try to go beyond mere information giving and try to involve the audience in solving the problem by encouraging the completion and carrying of universal organ donor cards. Legislation has been enacted in all fifty states making such cards legal instruments for the post mortem donation of organs. As I have mentioned, however, all organ procurement programs with which I am familiar also require family consent, although legally it is not required if a donor card is available. The success of organ donor cards in increasing the number of donor organs is minimal; relatively few donors each year are identified as card carrying donors. Our program has only one or two such donors each year out of 50 to 60 donors in our region. The primary problem, I believe, is that our death is a very fearful prospect for most of us. We defend ourselves against this fear by avoiding any activity which tends to confirm our mortality. Completing and signing a donor card affirms our appointment with death and, as a result, most of us never get around to getting or completing a card. Like most other organ procurement programs, we distribute donor cards --- as many on 10,000 a year. This is not a large number compared to our region's population of approximately 3.5 million people, however. In Pennsylvania we have also had donor cards distributed with drivers' licenses for several years, yet our program has not seen an increase in card carrying donors as a result of this program. A recent survey in Maryland, where the donor card is on the drivers' licenses, found that only 1.5% of the people chose to complete and sign the card (5).

Organ donor cards do have some utility. Their availability stimulates discussion and contributes to a positive climate of awareness regarding the need for organs. Many times I have been told by donor families that receipt of a donor card with a driver's license engendered a family conversation, during which the deceased indicated his willingness to be a donor. These discussions are remembered at the time of death if organ donation is offered to the family, even though the deceased did not fill out the card. These families inevitably donate.

I have always believed that public education should include the subject of brain death, as well as organ donation and transplantation. Many of my colleagues do not agree with me, believing that the subject is too complex for the lay public to comprehend or that there is a danger of brain death being misconstrued as so-called "transplant death". This latter possibility exists primarily because of the medical profession's hesitancy in educating the public about brain death, a syndrome which is undoubtedly clinically associated with many more non-donors than donors. If brain death is mentioned only in conjunction with organ donation, so the argument goes, the public will believe the syndrome is diagnostic of death only when the organs are sought, that brain death is not "real" death but a shortcut designed to make organ recovery possible.

On the contrary, I find the public intuitively sophisticated and ready to comprehend that death of the brain is diagnostic of death of the person if they are given accurate information and the discussion is in lay terms which they can comprehend. Not being candid about brain death and its relationship to organ donation is potentially very dangerous. If the public does not understand and accept it, they are much more likely to experience suspicion and disbelief when they are faced with it. We are all more ready to reject what we have not heard of or do not understand.

Our emphasis on brain death education led us to seek enactment of legislation giving statutory recognition to brain death. Such legislation was not necessary to give legal standing to the syndrome as diagnostic of death, but was perceived as a means of educating the public. Public acceptance and passage of

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the brain death bill also, we hoped, would reassure a medical community fearful of putative public inability to understand and accept brain death. Our program worked collaboratively with the other organ procurement program in the state, the Delaware Valley Transplant Program, Philadelphia, the Pennsylvania Department of Health, the Pennsylvania Catholic Conference, the Pennsylvania Medical Society and the Hospital Association of Pennsylvania in aggressively seeking passage of the Uniform Determination of Death Act during 1982. We conducted a vigorous letter writing campaign seeking medical professional and public support, sought and received press attention for the Bill and testified at legislative hearings in support of passage. This educational effort was very successful, surprisingly little opposition was encountered and the Bill was passed during December, 1982. It is too early to tell whether or not the passage of this legislation will reassure the many physicians who hesitate to cooperate in organ procurement because of their fear that the public cannot accept death pronounced on the basis of destruction of brain function.

Perhaps one of the less well recognized functions of public education is the impact it has on health professionals. Doctors and nurses are also media consumers and public education can help to persuade health professionals that organ procurement and brain death are acceptable to the general public. The health professions are generally conservative and frequently tend to follow rather than to lead public opinion. Yet, I am sceptical of the utility of costly advertising efforts as I have seen them employed in

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this area in the past. Professionally produced public service announcements focusing on organ donation have almost always been directed toward the educated, white middleclass audience. Much more effective, I believe, would be programming and public service announcements directed toward segments of the population, i.e., working class ethnics, black Americans, Spanish-speaking Americans and other population subgroups. I feel that little is to be gained through educational efforts which do not employ the mass media; highly labor intensive public speaking campaigns directed toward schools and civic groups, for example, have little impact. The American Advertising Council does take on projects for non-profit organizations and activities. Perhaps this group of professionals could be prevailed upon to contribute time and talent to the production of effective mass market public education.

Since, in my experience, approximately four out of five families offered the opportunity to donate will decide favorably, I believe that the most effective allocation of current funding available would be to invest in the education and motivation of health professionals to recognize and refer potential donors. Despite very heavy favorable media attention to organ donation, transplantation and brain death in the greater Pittsburgh area, no more than one out of ten donor referrals to our program is at the request of the family. The death of a loved one is so painful, the families are generally so preoccupied with their loss, that they do not think of organ donation. It must be offered to them. The role of the physicians and nurses who care for the patients and are in a position to recognize donors and to refer them to the local organ procurement programs therefore becomes critical. The education of health professionals and the establishment of institutional policies which will enhance organ donation should, I believe, be the primary areas for the investment of time, energy and money. I must recognize, however, that many of my colleagues do not agree with me.

This is the philosophy which has been followed at both organ procurement programs with which I have been associated as Director. I joined the newly formed Transplant Foundation at the University of Pittsburgh School of Medicine in January, 1978, after nearly four years with the Delaware Valley Transplant Program. Both programs were established at the outset as independent not-for-profit corporations governed by Boards of Directors composed of physicians closely involved with transplantation at associated university medical centers. Financial and corporate independence allows for flexibility in establishing and implementing programs designed to achieve procurement goals. This Committee will hear evidence presented by other expert witnesses which strongly suggests that such independent organ procurement agencies are more economical and more successful than are programs which are functions of hospitals or universities.

In describing the philosophy and the programs which I have found successful in organ procurement, I will focus on the Transplant Foundation at the University of Pittsburgh and our efforts during the past five years. Although kidney transplantation had been initiated by the University's School of Medicine in 1964, the program had remained relatively small until it was

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reorganized in 1977 under the direction of Thomas R. Hakala, M.D. Growth of the transplant program had not been limited by the number of patients referred for renal transplantation, witness the fact that almost 100 ESRD patients were on our waiting list in late 1977. Instead, the major handicap had been the shortage of available kidneys. Until 1978, the University was entirely dependent upon kidneys which could be recovered at the University Health Center of Pittsburgh or could be imported from other centers in the nation. No organized effort existed to seek the collaboration of other area hospitals in recognizing and referring donors. In the fourteen year history of the renal transplant program at Pitt prior to 1978, only one donor had provided organs at a hospital outside the University Health Center. Clearly the community hospitals offered an untapped source of organ donors.

Two major programs were planned and implemented during 1978 for developing organ procurement at approximately 90 hospitals in a geographic area including western Pennsylvania, eastern Ohio and northwestern West Virginia: (a) an educational program for health professionals and (b) a comprehensive organ retrieval program, which would provide 24 hours-a-day services for the coordination of the donation process and for the surgical retrieval and preservation of donor kidneys in outlying hospitals.

The educational program emphasized dissemination of information concerning the need for kidneys, donor criteria, evaluation and management, the medicolegal aspects of donation and brain death, the psychology of grief and its effect on organ donation, the surgical techniques of organ retrieval and the services provided by the Transplant Foundation team. I was given responsibility for implementing this program.

We followed a five-step plan. First, the need for educational materials was recognized and appropriate brochures, posters, phone stickers and handbooks were developed. Secondly, a direct mail campaign utilizing personal letters and follow-up phone calls was initiated to establish contact with physicians in influental positions within area hospitals for the purpose of scheduling educational programs. Third, presentations were scheduled and carried out at meetings of medical staffs, critical care nurses and hospital administrators. Fourth, in those hospitals in which contacts could not be made with supportive staff through mail and phone efforts, I sought cooperation and speaking opportunities through unscheduled individual contacts with key hospital personnel. Fifth, follow-up personal contacts were planned and carried out on a regular basis to strengthen and maintain the level of awareness and to facilitate the formation of strong purposeful relationships with important keystone professionals.

We have continued to follow this program throughout the past five years. Experience has proven the value of personal contacts through phone, mail and direct visits with physicians and nurses in critical care areas. Too frequent contact can be interpreted as unwarranted invasion of professional responsibility, whereas very infrequent contacts do not maintain the visibility for organ donation we strive to achieve. We find that contacts approximately four times a year are most effective. An effort is made to enhance identification of these health care professionals with our program through the distribution of inexpensive calendars,

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penlights, pens and other items with our logo, name and telephone number. Personnel changes in area hospitals frequently necessitate repeat educational programs.

Our efforts to acquaint physicians and nurses with our need for organs and to excite them about the possibility of cooperating with us were and are today met with a variety of responses. Many health professionals were warmly receptive, hungry for information and eager to assist for purely humanitarian reasons. Many others were indifferent and unresponsive or aloof and unwilling to help because of perceived medicolegal problems. A few were interested in helping because they anticipated that cooperation would possibly be used to their benefit politically. If their needs were not met, they quickly lost interest. And, finally, a very few were openly hostile; more than once I was summarily ejected from a hospital or told that I was presumptious for seeking cooperation in establishing our donor program in a hospital. One becomes rather thick-skinned and if one approach does not work there are usually other approaches which can be taken. Almost always we can find someone in a given hospital who is interested, receptive and helpful. What I want to emphasize, however, is that the direct humanitarian appeal is sometimes not effective in securing cooperation of health care professionals.

Health care is not unlike other areas of human endeavor in that it is affected by politics, power struggles, inertia, fear, vanity and money. Motivation is often, but not always, complex, and frequently includes factors other than a desire to help others. Development and the growth of a donor program must recognize and accept this reality and, if possible without compromising individual and program principles, work with it or, if necessary, work around it.

The most important inducements which are effective are the solace organ donation provides the health professional and the humanitarian appeal of helping others, both the donor family and the transplant recipients. Health professionals, like all of us, dislike failure. The death of a patient is an assault on their feelings as caring people and an affront to their professional competence and identity. Their tendency in the face of patient death is often to attempt to distance themselves emotionally from the pain of failure. What we can offer doctors and nurses is a way of diminishing pain of failure. We do not put it that way to them, of course. We talk instead of the lives of the recipients which can be saved and the solace the family can realize through transplantation of the donor's organs. There is genuine satisfaction for a physician or nurse in helping both the family and the recipients through participating in organ donation, but what most get out of the experience, I believe, is a restoration of their own self-regard and emotional equalibrium. Participating in organ donation tends to diminish their sense of loss and failure. But, again, for some this is not enough. And for a very few, nothing appears to be enough to secure their active involvement.

The personal relationship developed between the representative of the organ procurement team and physicians, nurses and other hospital staff is also a major factor in developing an organ procurement program. In our program, the organ procurement coordinators (there are now four of us) are the most visible of the team members. We make initial contacts, provide the educational programs for doctors and nurses, receive donor referrals, collaborate on-the-scene throughout the entire donor process (evaluation, management, discussions with family, surgical removal of the organs), call, write and return in person to provide feedback about the transplant outcome. In the process we strive to develop a relationship based on trust, collaboration, recognition, personal regard and shared experience. The strength of the relationship enhances and sustains other motivational factors which may be operational.

Nothing succeeds like success, however, and a positive experience of being involved in recovering organs from a donor is very reinforcing for most physicians and nurses. Their sense of satisfaction almost always guarantees their future support. But, in order to provide this kind of positive experience, the entire process must be handled efficiently, tactfully and knowingly from beginning to end. The second major component of our program, the system for coordinating the donor process and recovering the organs is based on our belief that only transplant professionals have the time, committment and attention to detail which are necessary to ensure that the experience and the outcome are both positive. Some organ procurement programs appoint a nurse or physician on the staff of a community hospital to coordinate organ donation in that institution. Some programs also train local non-transplant surgeons to remove kidneys for shipment to the transplant center. We feel that reliance on indigenous health professionals is fraught with too many opportunities for error, misunderstanding and omission of important procedural steps. The organ donor process from beginning to end is a very complex one, involving critical clinical, medicolegal and psychological variables.

Problems, when they occur, need to be handled expeditiously and sensitively. If they are not the concept of organ procurement suffers and the enthusiasm for cooperating with our program is damaged. For these reasons, we believe it is necessary to have one of our coordinators present in the donor hospital whose sole purpose is to make the donation process work. Similarly, in the Operating Room our transplant surgeons are responsible for performing the donor surgery. The techniques are specialized and not understood by untrained surgeons. Additionally, the transplant surgeon's committment to a positive experience for the donor hospital's staff and the recovery of viable organs is more focused because he knows that the success of his program and the well-being of his recipients is directly at stake.

In summary, the establishment and success of an organ procurement program is not an enterprise which lends itself to a mechanistic or bureaucratic approach. As with any endeavor which requires collaboration of people from disparate professions with differing agendas and dissimilar institutional loyalties, organ procurement requires constant attention to the establishment, maintenance and repair of a delicate fabric of relationships, as well as dissemination of substantive information and technical competence.

Yet, no program is so successful that it can sustain itself solely with the organs recovered in its immediate region. Organ sharing between 110 organ procurement programs has developed over the past dozen years in response to need and technical capabilities. Fully half the kidneys transplanted today have been surgically recovered by distant procurement programs and transported to the transplanting center. Kidney sharing is facilitated by our technical ability to preserve these organs for 48 hours and sometimes longer. Since kidney transplantation is seldom if ever life-saving therapy and since, until recently, demonstrably improved transplant survival occurred when attention was given to matching donor and recipient tissue types, the sharing of kidneys on the basis of computer matching of immunologic factors has been enthusiastically supported by almost all centers. The United Network for Organ Sharing (UNOS) is an informal network of approximately 130 transplant and organ procurement programs which register their patients waiting for renal transplants on a central computer owned and operated by the South-Eastern Organ Procurement Foundation (SEOPF) in Richmond, Virginia. SEOPF itself is a regional cooperative organization of 39 transplant programs, although its computer provides nationwide services for distribution of kidneys. The concept of computer matching for kidneys must not be misunderstood to mean that the computer directs the placement of that available kidney. Instead the computer merely sorts through the thousands of potential recipients to identify those which appear to be suitable matches. The sending center then selects the recipient center(s) to which it may wish to offer the available organ, contacts that center by phone and makes arrangements to transport the kidney if it is acceptable. Sharing of kidneys is not infrequently influenced by non-immunologic factors, such as the proximity and close relationship between sending and receiving centers.

The emergence of extrarenal organ transplantation as an acceptable therapy for end-stage heart and liver failure patients has in the past few years resulted in a modification of this informal organ sharing effort: the collaboration of two or three programs in surgically recovering organs from a single donor. In this form of sharing the donor is identified in a regional hospital of one program. The host program is almost always eager to recover the kidneys, but has no use for the extrarenal organs. Rather than see the organs wasted, the host program invites one or two other procurement programs in need of extrarenal organs to fly to the donor hospital for the purpose of retrieving the heart and/or liver. In this model the on-scene coordination of all clinical, medicolegal and logistics aspects of the donation process are handled by the host program coordinator. Telephone communication between the host coordinator and his colleagues from the extrarenal center(s) facilitates the carrying out of specialized requirements for the extrarenal centers prior to the convergence of all of the teams in the donor hospital Operating Room. All of the programs participating in organ recovery share in assuming the responsibility for the costs.

The Transplant Foundation at the University of Pittsburgh did not initiate intercenter collaborative organ retrieval (that distinction belongs to the University of Colorado and the Medical College of Virginia), but it unquestionably has the most experience in this form of organ (or, more properly, donor) sharing and has developed the system far beyond its early stages.

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This form of intercenter collaboration was first attempted by Pitt in 1980 with the inauguration of our cardiac transplant program and has become a commonplace activity during the past two years with the relocation of the nation's largest liver transplantation program to Pittsburgh. Our program was unable to generate sufficient numbers of donors for heart and liver transplantation within our own region and necessarily turned to other programs with a request for help. The need for help from other programs is not just a function of the number of available donors locally. We have a rather large donor program and annually recover kidneys from 50 to 60 donors in our region. For several reasons, an available donor may not be suitable for heart or liver donation. First, patients accepted for heart and liver transplantation are terminal and will die within days or weeks unless successfully transplanted. There is often no time to wait for a local donor. Secondly, unlike kidneys, heart and livers must come from size compatible donors. Especially in the case of pediatric recipients, this presents a major problem since relatively few small children succumb to brain death. Our liver transplant waiting list now includes over 30 potential pediatric recipients under the age of five years. Intercenter collaboration is imperative especially for these youngsters.

Our experience in seeking the cooperation of other procurement programs recapitulated our experience in asking for the help of hospitals in our own area. A few programs enthusiastically came to our aid immediately, most were suspicious and slow to respond and a very few were indifferent or hostile and totally uncooperative. The primary concern initially voiced by our colleagues at other programs was their fear that the surgical technique required for extrarenal procurement would jeopardize the quality of their donors' kidneys. This is not true but time, persistence and published data were required to convince many initially reluctant programs. We still find that there are many organ procurement programs within the eastern half of the United States which are unwilling to collaborate with us in the recovery of extrarenal organs. Some of these programs are merely insular, some are unwilling to help because of the extra effort required and some are reluctant to work with us because they fear our involvement will somehow compromise their own procurement efforts.

Although intercenter collaboration was difficult for us to establish, the concept has become increasingly popular. The statistics reveal our success. During 1981, we received 175 referrals of extrarenal donors from other programs and were able to recover 20 livers and 9 hearts in cooperation with distant renal procurement teams. In 1982, we received over 520 referrals from other programs and recovered 63 livers and 18 hearts with outside help. Three-fourths of the livers and four-fifths of the hearts transplanted at the University Health Center were recovered through the generous collaboration of other regional procurement programs. We are proud, too, that Pittsburgh is also a major provider of extrarenal organs to other centers. When we are unable to utilize an available extrarenal organ from a donor in our region, we always seek to work collaboratively in the recovery of these organs with other programs in need.

One of the major factors which aided us in developing intercenter cooperation was the opportunity for communication and the development of trust afforded by the professional association of organ procurement coordinators, the North American Transplant Organization (NATCO). Workshops on extrarenal organ procurement sponsored by NATCO provided an opportunity for concerns to be discussed and resolved. NATCO's annual training course for procurement coordinators provides intensive orientation through extrarenal procurement for new procurement personnel.

NATCO has also been a major force for the sharing of extrarenal organs. The major system used by procurement personnel to locate recipients for available extrarenal organs is sponsored by NATCO. At this time, approximately 17 transplant centers are involved in extrarenal organ transplantation in the United States and Canada. This number will become swollen during the next several months when at least five additional centers will inaugurate heart transplant programs and another six centers will begin transplanting livers. Last year, NATCO recognized the problem faced by organ procurement personnel in locating suitable recipients for extrarenal organs which may become available in local community hospitals. The UNOS computer system has great utility in helping to distribute kidneys, but is much less effective in the area of extrarenal organ sharing. Because of very limited capability for preservation of extrarenal organs (hearts can be preserved for no more than 4 hours and liver for approximately 10 hours), these organs cannot be removed from

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the donor before a suitable recipient is identified. Transplantation must occur immediately after the donor surgery. Size, blood type compatibility, geographic distance and urgency of need are the primary factors considered in coordinating recipient selection of extrarenal organs. Procurement coordinators who receive a donor referral during non-office hours or who are evaluating a donor at a community hospital and wish to discuss extrarenal donation with the donor family cannot access the UNOS computer to review current extrarenal needs across the country. NATCO recognized the problem and established a 24 hour-a-day telephone service for informing organ procurement programs of extrarenal needs. This free, volunteer service utilizes a recorded message system which can be accessed from any phone in the United States or Canada. Updated as needed (usually once or twice a day) the recording lists by center the type of organs needed, a priority status code indicating urgency of recipient need, the donor criteria (size, weight, blood type), geographic limitations to procurement, the name of the procurement coordinator to be contacted and the phone number of each participating extrarenal center. Fifteen extrarenal centers now use the system to acquaint organ procurement programs with their donor needs.

During the first six months of service, the NATCO 24-ALERT System (the name is taken from the System's mnemonic phone number) facilitated the recovery and transplantation of 30 hearts at 9 centers, 48 livers at 5 centers and 1 heart-lung bloc. Success of the 24-ALERT System and temporal limitations which prevent heart and liver procurement much beyond 1,000 miles from an extrarenal center have prompted NATCO to plan to divide the System into two complimentary geographic components. Within the next month a 24-ALERT WEST will be established to handle the western half of the country, while the original System will continue to convey information of relevance for the eastern half of the nation.

The System is not perfect but it works better than anything else available at this time. The UNOS computer, in fact, is used only infrequently for extrarenal organ sharing because of the greater effectiveness of the NATCO 24-ALERT System. As is the case with the UNOS computer program for kidney sharing, the current System provides information to the donor program staff and leaves up to them the decision concerning which extrarenal program is to be contacted. Undoubtedly some extrarenal programs are often not contacted because of factors unrelated to the urgency of their need. Center-specific problems with the quality of their procurement services are a major impediment, for example, for some extrarenal programs. No distribution system will be effective which attempts to compel cooperation between programs which do not trust one another.

Inter-regional extrarenal procurement is expanding rapidly. The University of Pittsburgh alone has worked cooperatively with over 40 other organ procurement programs during the past two years. On 12 occasions we have participated with two other programs in simultaneously recovering organs from a single donor. At this time the necessary trust in the technical competence of other transplant surgeons which would allow distant procurement and sharing of extrarenal organs (rather than donor opportunities) is not well developed; most extrarenal transplant surgeons still desire to have donor organs removed by members of their own team. With experience and time, however, this inhibition will be overcome and hearts and livers will be exchanged as kidneys are now.

One major problem will probably continue to exist for the foreseeable future. Because of the delicate nature of lung tissue, long distance procurement of heart-lungs and single isolated lungs now require the tranportation of the donor from the donor hospital to the center where transplant surgery will be performed. Recent success with the transplantation of heart-lung blocs warrants continued efforts in the transplantation of these organs. The willingness of most organ procurement programs to transport a local donor hundreds or thousands of miles to an extrarenal center for the recovery of heart-lungs or isolated lungs is strongly inhibited at this time by the fear of the procuring program that the quality of the kidneys will be jeopardized. Another factor limiting the availability of these organs is that many families which are willing to donate are unwilling to subject their loved ones to transportation to the donor center for organ retrieval. The University of Pittsburgh and Stanford University have the only heart-lung transplantation programs in the United States and both are seriously compromised in their ability to offer heart-lung transplantation to the many candidates for this surgery because of the shortage of suitable donors. Montefiore Hospital, New York City, has a similar problem in developing their lung transplantation program.

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The current system for the procurement and sharing of kidneys and extrarenal organs is essentially sound, I believe. The existing system of regional procurement programs is in principle the most effective means of cultivating the growth of donor programs at the community hospital level. Regionalization facilitates the personal contacts which are essential and regional idiosyncrasies are best recognized and responded to on a regional basis. Inter-regional collaboration will continue to grow as need and familiarity with the benefits of donor and organ sharing increase. Yet the fact that no more than one-third of the potential donors in this nation now yield organs for transplantation indicates that the system for organ procurement at the regional level needs strengthening, especially at its weakest point: the interface between the organ procurement programs and the health professionals in the community hospitals who are in a position to recognize and refer donors. I have the following recommendations:

(1.) It is time that transplant and organ procurement professionals seek the help of others outside the transplant community. A national task force should be formed of representatives of organ procurement and transplant specialty groups and other significant health professionals' organization to identify problems inhibiting referral of organ donors to regional programs and to recommend solutions on a national level. Such a task force should include leaders from organizations which represent physicians and nurses likely to encounter donors, i.e., neurosurgeons, neurologists, critical care physicians, emergency physicians, pediatricians, critical care nurses, as well as leaders from organizations of hospital administrators and other relevant groups.

(2.) Rules and regulations should be enacted on the state and/or national level which would require that every hospital seeking certification (a) enact a policy and operational protocol for the determination of brain death; and (b) develop a policy and protocol for the recognition and referral of potential organ donors to the nearest regional procurement program. (In Pennsylvania, with the support of the Secretary for Health, efforts are now underway to have both of these regulations adopted by the State Department of Health as requirements for hospital certification.)

(3.) A financial incentive should be built into the federal Medicare reimbursement system which would reward hospitals from which post mortem donor kidneys are recovered for transplantation. No new legislation should be required, since Medicare now funds renal transplantation and kidney procurement. This should be especially attractive to the taxpayers and the federal government since kidney transplantation is considerably less expensive than chronic dialysis. (Most post mortem kidney donors are also potential extrarenal donors and this incentive system would also enhance opportunities for extrarenal organ procurement.)

(4.) Areas of this country still exist which provide few if any organs for transplantation. The problem in part is the failure of the regional organ procurement programs effectively to educate physicians and nurses. Strengthening education for health professionals is essential. One step in this direction has recently been taken by NATCO, which has established a 24 hour-a-day organ donor information and referral hotline for doctors, nurses and other hospital staff who have questions about donation or want to refer potential donors but do not know how to contact their local procurement program. Staffed by trained organ procurement coordinators, the hotline (dial 800/24-DONOR) needs wide exposure in the medical community to be effective. Support for this and other efforts to strengthen professional education is sorely needed.

(5.) Public education efforts should be stepped up, with emphasis given to developing mass media educational opportunities focused on subgroups of the population. The National Advertising Council should be asked to take on a national project for public education.

(6.) My final suggestion is one which should be self-evident from my testimony. There is a real need for the accumulation of data on organ donation, organ distribution and transplantation. Some data is now collected on renal donation and transplantation by the Health Care Financing Administration, but no

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figures are available for the country as a whole concerning the number of potential donors, the number of potential donors referred to organ procurement programs but from whom organs are not recovered, the number of extrarenal organs needed, recovered and transplanted. Some very practical questions need to be answered. For instance, how many suitable pediatric donors between the ages of six months and five years are potentially available? The number of small children being referred for liver transplantation is growing geometrically; we may be faced with the fact that there will never be a sufficient number of younger donors to meet the need. We won't know unless we investigate.

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Mr. Gore. Thank you very much, Mr. Denny. I commend your entire remarks to the attention of those reading this record and your recommendations will no doubt, many of them be included in the subcommittee's report.

Dr. William Pfaff, past president of the South-East Organ Procurement Foundation at the University of Florida College of Medicine in Gainesville, and a noted kidney transplant specialist in his own right. We are delighted to have you here.

Please proceed.

Dr. Pfaff. Thank you. I was asked to appear today to describe the South-East Organ Procurement Foundation [SEOPF]. SEOPF actually has been enlarged from its original membership of eight to some 40 members.

Those of you who live north of here will be surprised to learn that New Jersey is also in the Southeast, as is Indiana. So the rough boundaries——

Mr. Gore. We are an ambitious region.

Dr. Pfaff. The rough boundaries are New Jersey to Indiana, Louisiana to Florida. Almost all of the programs that are transplanting and procuring organs in this areas are members of our foundation.

SEOPF was established with the hope and expectation that tissue typing and tissue matching would result in improved graft survival. That was the first premise.

Second, there was a realization that an excess of supply at one site might coincide with a need at another site, that there was an advantage to mutual education and a discipline that was dramatically unfolding. Finally, there was a need for uniform tissue typing laboratory practices. As the organization has matured, it has continued to work at these goals, and then has established some others in a variety of activities.

The current means of exchange is heavily dependent upon our computer network. We list, from the members alone, something in excess of 2,200 patients.

Approximately one-third of the patients who are being transplanted in the country receive their grafts among this membership of some 40 institutions.

The means of distribution of kidneys is principally on the basis of tissue typing characteristics. We are trying to take advantage of the immunology that we have gradually uncovered over these years in order to provide a more successful graft, for there are some individuals who absolutely need a well-matched transplant in order to be successfully managed.

The computer network distribution system has been expanded to the rest of the country, and the organization that is an outgrowth of the SEOPF technology is called UNOS [the United Network for Organ Sharing.]

Now some 138 transplant programs nationwide, thus, are using this single means of distributing kidneys. When I left Gainesville yesterday, on the plane with me there was a kidney that was destined for Minnesota. Another had left on the earliest plane from Gainesville to go to Mississippi. By the same token we expect that Minnesota is going to return the favor for the same purpose, namely, to provide, again, a well-matched organ.

In practical terms if a kidney becomes available at the University of Florida or one of our nearby hospitals—we are in a semirural area—that we tissue type the donor, look at the computer readout and first priority, and that is to distribute the well-matched organ, irrespective of local need.

We run the computer program and identify the potential recipients who are listed in priority of their organ matching characteristics and then call the appropriate center. Each of the centers have 24-hour numbers and 24-hour personnel to advise them of this opportunity.

The level of activity of SEOPF members, included 604 kidney transplants from July 1 through December 31, 1982. During the same time period, half again that number of organs were procured. In other words, the transplant rate is 1,200 per year, the procurement rate is 1,800 per year. Thus there is an excess that is generated within the region and that is distributed to non-members as the net of about 250 or 260 excess kidneys per year.

The total incidence of sharing amongst the donating centers is some 59 percent. The majority of the kidneys that are procured in the Foundation are shared with other centers, both within and without the Foundation.

The other areas in which we have become interested in is scientific data. Somewhere along the line we needed to find out what we were doing. The points that Mel Williams made to you earlier today regarding the five factors that have import and the varied success of transplantation are factors that have been covered, uncovered, sustained and demonstrated individually in other programs.

All of that information was generated within one program and that was from the cooperative efforts of the SEOFP membership, so that we achieved some specific knowledge about transplantation, about organ preservation, sharing, and procurement as a consequence of sharing our information.

In 1973, with the institution of the medicare law that covered renal failure, the funding for the voluntary registry that transplant programs have maintained for a good number of years ceased.

We were promised a medical information system. That has never happened. The only sources I have for making decisions about patients are the SEOPF data that addresses only transplant patients and my local network, that is, the Florida End-Stage Renal Disease Network. We have excellent data on every dialysis and transplant patient in the State of Florida. I know the relative risks of dialysis and transplantation, of different modes of transplantation, as that is expressed in age, causative diseases and also associated diseases.

I would urge those of you who are interested in having information available to make such decisions that you reconsider the efforts that have been suggested in some areas of our own Government to cease funding of the networks. To me, it would be crippling.

Transplantation of heart, liver and pancreas is varied in this country, rapidly growing. You heard a number of people describe a number of existing programs.

Frankly, within our own foundation we have not kept up with it. We have not established a program for sharing these organs. We cannot address the costs of distribution of other organs, at least as an addition to the elements of exchange to the End-Stage Renal Disease Program. We would have to establish some other form of funding to do that, because of the disallowance you have heard discussed earlier today.

Can the basic system be used for organ exchange? Yes. The means by which we exchange organs really is adaptable, I think, to almost any organ.

There are differing needs in terms of the ability to maintain the organ outside the donor, even in using the preservation techniques we have today. The heart is very urgent, the pancreas, perhaps, the most urgent of all. It appears that the liver can be preserved for at least a number of hours. The kidney, can be sustained for 1 to 3 days. Each of those developmental problems of organ preservation is going to put different kinds of restrictions on us in terms of both procurement and, most importantly, sharing of organs.

Yet we come to that subgroup of our patient populations who absolutely need a well-matched organ in order to be successfully transplanted, and we need to address that question as we proceed.

We are increasing our success at all forms of transplantation. Each one of us looks at our own program and questions. "Have we done better this year?" We are proud if we have; we are disappointed if we haven't—we are dashed if we haven't.

The economics of transplantation are a matter of continued conversation in your sphere and in ours. For these new areas we don't have a solution. We have come to you for a solution. We need to expand this dialog, from successful kidney transplantation to increasing success in other areas.

The problems, as I see them, are identification of additional appropriate transplant recipients. That is based on the delivery of sound, scientific information, both to patients and to other professionals.

I think that you have heard that often enough. I would not reiterate further.

We are doing a good job of kidney procurement in our area of the country. I think we are doing a fairly good job in terms of extra organ procurement.

I would ask whether that is the product of our cooperative work, of our group effort, of our mutual pride, because I think that that is something that might be exported to other areas of the country.

There are very few large regional organizations. They tend to be metropolitan or a small area. Yet, much of our ease of working with one another has been through sera exchange, through the histocompatability laboratories and through our computer network.

I would favor expansion of the regional concept with interregional cooperation. We have some patients who have uncommon blood type, uncommon tissue types and their opportunity for a matched graft even within our rather sizable program may be infrequent. Thus, expansion of the number of cooperating centers will expand the potential for cross-matching between donor and recipient, we will have a much better likelihood of getting these long-waiting individuals a successful transplant.

Thank you.

Mr. GORE. Thank you very much.

[The prepared statement of Dr. Pfaff follows:]

TESTIMONY OF WILLIAM PFAFF, M.D., CONCERNING ORGAN SHARING TRANSPLATATION

SUMMARY OF TESTIMONY OF WILLIAM W. PFAFF, M.D.

CONCERNING ORGAN SHARING IN TRANSPLANTATION

PRESENTED TO THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY
UNITED STATES HOUSE OF REPRESENTATIVES

APRIL 13, 1983

The success of transplantation can be improved by inter-institutional cooperation. The Southeastern Organ Procurement Foundation (SEOPF) is an example of a voluntary organization of forty transplant centers. The Foundation has created a computer network to facilitate organ exchange between 140 transplant programs, listing approximately 5,500 prospective renal transplant recipients. Through the membership's tissue typing laboratories, uniform techniques generate information that allows priority distribution of organs to individuals who are most likely to benefit from the advantages of histocompatibility matching. The efforts of the membership have resulted in advances in organ procurement and preservation, professional and public education, and scientific information. The technology is adaptable to other organs.

Mr. Chairman and members of the committee, I am William W. Pfaff, M.D. of Gainesville, Florida. I am a professor of surgery at the University of Florida, Director of the Kidney Transplantation Program. I am the immediate past President of the Southeastern Organ Procurement Foundation (SEOPF) and am a member of the Board of Directors of that organization. I have been asked to describe existing organ sharing, specifically as practiced in SEOPF.

Under the leadership of David Hume and Bernard Amos, SEOPF was founded in 1968 by several transplant programs that were predominately mid-Atlantic in location, to explore the feasibility and effectiveness of organ sharing to:

a. Verify the worth of tissue typing to improve graft survival in the general transplant population.

b. Provide an opportunity for transplantation for individuals who required a well-matched graft.

c. Aid in the development of organ preservation.

d. Foster effective use of kidneys when a recipient was not available locally.

e. Develop uniformity of tissue typing techniques.

There has been growth of SEOPF over the ensuing fifteen years. There are now forty members embracing an area that extends from New Jersey to Indiana to Louisiana to Florida. The membership performs 1,200 cadaver transplants per year, approximately one-third of the national activity and serves approximately one-third of the dialysis population suffering from end stage renal disease (ESRD).

With maturation of the organization, the original efforts have become more intense and our purposes are broadened.

TISSUE TYPING

During the past decade, tissue typing has become ever more complex. There are new antigen systems, which are surface markers on cells, that allow identification of similarities between a potential donor and recipient. Successful organ exchange depends on the capacity to identify these antigens with equal facility in exchanging institutions. Participating member laboratories must mature in their capability at an equal pace with trend-setting institutions. SEOPF has initiated peer review amongst its members by on-site workshops, mailed cell exchanges that allow grading of results to ensure uniformity, inspections of laboratories that have undergone change in personnel or that have suspected deficiencies in performance.

ORGAN MATCHING

As the Organization and the pool of prospective recipients grew, automated identification of the most appropriate recipient became necessary. In an evolutionary fashion, computer programs have been refined to allow participating institutions to identify all prospective recipients for a particular kidney. The putative recipients are categorized by shared antigens listed in order of greater to least.

Prospective recipients are identified by name, age, blood tissue typing data, antibody status, duration on the computer list, location of the recipient center and telephone numbers for contacting the responsible institution.

By general agreement, the first priority for sharing is a perfect tissue typing match. At lesser grades of sharing, other factors assume priority, including distance, multiple candidates in one center and additional immunologic factors.

Unless delegated, as will be discussed further, the donor center maintains responsibility for selecting a prospective recipient center and transporting the organ thereto.

CROSS MATCHING

One barrier to a successful transplant or the culmination of an intended sharing is the occurrence of antibodies, proteins that are capable of injuring foreign antigens. As a result of blood transfusions, pregnancy, or prior transplants, a patient may generate antibodies that are capable of killing the cells of other individuals. Of patients now listed in the computer, forty-six percent have antibodies directed against greater than sixty percent of the general population; twenty-seven percent have antibodies against an excess of ninety percent of the population.

For economy of dollars, time, and most important, the successful use of organs, it is important to be able to predict whether the serum of a recipient at a distant center will or will not kill the cells of a donor. If so, this is a positive cross match and that recipient is eliminated for the same effect will be wrought on the kidney or other organ.

In SEOPF, we particularly circumvent this problem by sharing serum of prospective recipients who have highly reactive antibody so that the donor center has cross matching material at hand. In consequence the donor center performs preliminary cross matches on all prospective recipients in whom antibody might present a problem.

When sharing an organ with non-members, there is a greater possibility that a positive cross match will ensue. It would be desirable if the system described above or some other alternative could be adopted for inter-regional sharing.

ORGAN PROCUREMENT

All members of SEOPF assume a responsibility for organ procurement. The statistics for7/1/82 - 12/31/82 are expressed as follows:

Total cadaver kidneys procured	898	
Kidneys used in local center	277	31%
Kidneys shared in SEOPF	250	28%
Kidneys shared outside SEOPF	209	23%
Kidneys not used (local decision)	90	10%
Kidneys not used after sharing	72	8%

In the same six-month period:

New SEOPF patients registered on computer	689	
SEOPF patients transplanted	604	
Kidneys from local sources	277	46%
Kidneys from SEOPF	250	41%
Kidneys from outside SEOPF	77	13%

These data provide an overview of the relative success of organ procurement in SEOPF. Pertinent conclusions are that: a) Kidney procurement in the region outstrips transplantation; b) SEOPF is a net exporter of kidneys, providing more kidneys to non-members that receiving same; c) two-thirds of kidneys obtained in SEOPF are being shared; d) the discard rate of unshared kidneys is probably acceptable. (Note: Kidneys are discarded for a variety of reasons, including anatomic or functional abnormalities, systemic findings in the donor, or failure to identify an appropriate recipient.)

The rate of organ procurement has steadily grown, and the ratio of transplants to new patients has decreased.

SCIENTIFIC ACTIVITIES

In the mid-70's, it was recognized that our combined efforts could potentially answer many of the vexing questions that were raised by the varied processes and circumstances that attend the complex steps that are involved in organ transplantation. These included patient survival statistics, graft success, differing drug protocols, transfusion policies, means of organ preservation, import of tissue typing characteristics in different patients. In the absence of a national information registry, this pooled information has become an important resource for understanding the changes that are occurring in transplantation success and to allow comparison of individual programs with a broader experience. Multivariant analysis has been applied to gauge a variety of risk factors, so that one might modify the circumstances under which one might proceed with a transplant. A number of important reports have added assistance in answering our constant queries as to the effect of variables in patient selection and management.

Parenthetically the data bank is currently limited to transplant patients, lacking information on the majority of ESRD patients who are managed by dialysis. At present, comparative data is available only through the ESRD networks. In my own state of Florida, I depend on the Network 19 data to help make the judgment as to the relative risks of various modes of dialysis and transplantation, including information as to the major risk factors. I thus strongly applaud the efforts of those members of the House of Representatives who favor continued and augmented funding for the Networks. The information derived has fiscal and rehabilitative import.

INNOVATIONS

In 1977, the technology of computer exchange was made available to SEOPF non-members by creation of an entity known as UNOS, the United Network for Organ Sharing. The cost is limited to the purchase of a terminal, direct charges for telephone and computer time, and a minimum fee for the accountable administrative expenses to maintain this service. Currently 100 UNOS programs list approximately 3,000 prospective recipients so that the combined UNOS-SEOPF listing includes 140 programs and 5,500 patients. Organ exchange can thereby be facilitated amongst UNOS members as well as between SEOPF and UNOS members.

A more recent experiment was the establishment of a 24-hour staff at SEOPF headquarters in Richmond, Virginia. The aim was to use these individuals to make the many phone calls that are often involved in the placement of a shared kidney, to arrange transportation, tying in with commercial airline computer services, to take advantage of charter flights that are underway to reduce transportation, and to free local personnel to pursue their many other tasks in organ procurement and professional and public education. This project was established as the result of a grant by the American Kidney Fund and continuation will be determined by the SEOPF Board of Directors in one month.

EDUCATION

The Foundation has been heavily involved in education of peers in transplantation, fellow professionals, our patients and the public. Manuals for tissue typing, organ procurement and organ preservation are regularly edited as innovations lead to improved techniques. We have undertaken dialogues with neurologic and neurosurgical colleagues to urge their cooperation, with critical care nurses and physicians. Ultimately we are dependent on the public's understanding. My own bias is that too little has been done and invested in this specific area.

GOVERNANCE OF SEOPF

Membership in SEOPF is voluntary and is institutional. Each participating transplant center names a director who has equal voice with all others at triannual meetings. An Executive Committee operates in the interval, their decisions affirmed by the full Board.

The day-to-day business of the Foundation is conducted by a salaried Executive Director and his staff.

The many tasks are initiated by committees addressing various distinct areas, that is tissue typing, education, procurement, et cetera. Participants include all disciplines involved in procurement, exchange and sharing -- histocompability technicians, nurses, coordinators, hospital adminsitrators, nephrologists, immunologists and transplant surgeons.

COSTS OF SEOPF

The current expenditure for maintenance of the Organization, expressed as cost per shared kidney follows:

General and Administrative costs	$243.91
Computer Network	167.53
Education	128.88
	$540.32

The current average cost of obtaining a kidney for transplantation is $7,729.00. This includes some of the expenses of evaluating patients for transplantation. The average cost of transporting shared kidneys is $392.00. SEOPF cost currently forms 6.2% of the total expense.

ASSESSMENT

1. Is this an effective system?

My program sought and has continued membership in the belief and now the conviction that membership would enhance our performance. This subjective conclusion is buttressed by ongoing improvement in graft survival in my own and other programs. While all of this is not directly attributable to membership, many of the innovations and certainly the emphasis on organ sharing has been a product of our membership.

2. Might these and similar approaches be used in other regions?

Many areas have sharing agreements and varied cooperation in other activities. The evolutionary broadening of the activities of SEOPF would seem to have merit to us, yet most of us do not feel that SEOPF as such could exist as a national organization because of cost and the loss of the extensive communications we maintain between institutions to complete our tasks. There would seem to be advantages to regional organization with inter-regional cooperation.

3. Can the techniques used in kidney sharing be applied to other vital organs?

The criteria for determining priority will differ and needs to be resolved by centers transplanting the heart, liver or pancreas. As the number of donating and transplanting centers grow, and as the potential recipient population swells, it would seem natural to take advantage of the computer network and the tissue typing laboratories that currently provide these services. SEOPF has recently initiated a formal extra-renal computer program, the cost and charge segregated from the kidney program because of Medicare considerations.

4. Is there increasing success in transplantation?

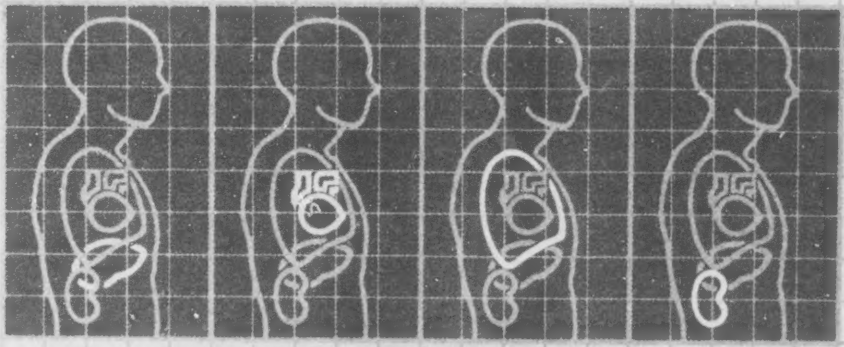
Not considering the potential for improved graft survival as a result of new immunosuppressive agents, SEOPF and Florida Network data both show substantial improvement in transplant function and decline in patient mortality. The Florida data comparing dialysis and transplantation in the most scrupulous and controlled fashion, shows no difference in the risk of dialysis and transplantation, and with broader considerations, shows advantage to transplantations in young individuals. The clear advantage of transplantation lies in reducing morbidity, returning people to productive lives, and reducing the annual expenditures for end stage renal disease.

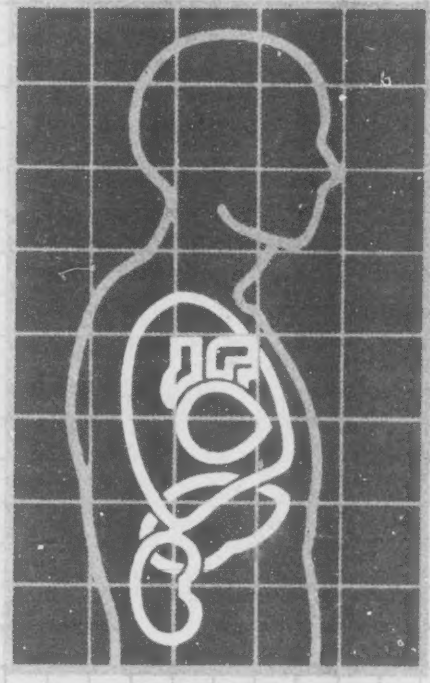
5. If the rate of transplantation should increase, can sufficient organs be obtained to meet needs?

The success of organ procurement efforts varies widely, and probably reflects the investment of time and personnel by transplant programs and voluntary agencies. Within SEOPF, more organs are being procured that are being transplanted by the membership. Isolating by subregions, those states that are effective in organ procurement demonstrate that within a broad population base there is sufficient organ availability to allow expansion of transplantation. It follows that similar effort by all programs would result in far more organs than are available now.

In addition to local efforts, I would hop that a centralized program using national media could be repeatedly addressed to the lay public to educate as to the feasibility and desirability of organ transplantation.

South-Eastern Organ Procurement Foundation





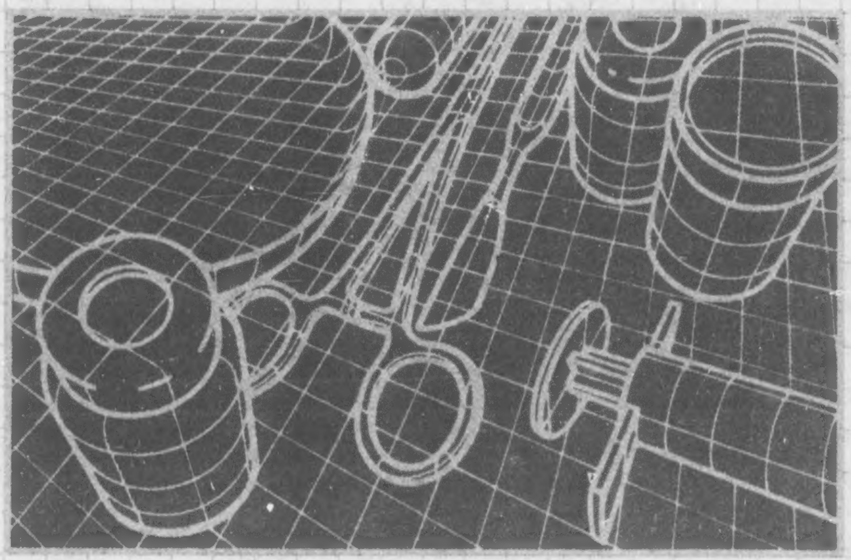
Transplantation: more than a surgical procedure

Organ transplantation has been one of the most dramatic medical achievements of this century. The success of transplantation has been brought about by advances in surgery, immunology, biochemistry, pharmacology, and bioengineering. No longer an experimental technique, transplantation is now the accepted form of therapy for many patients with irreversible loss of function of many of the body's vital organs and tissues.

Just as transplantation requires the cooperation of many disciplines within the hospital, transplantation is dependent upon the cooperation of many hospitals across an ever-increasing geographic area.

With over 60,000 kidneys transplanted worldwide, a firm foundation has been laid upon which transplantation can grow.

A vital force in this growth is the South-Eastern Organ Procurement Foundation, a unique collection of physicians, physician's assistants, surgeons, nurses, technicians, and administrators.

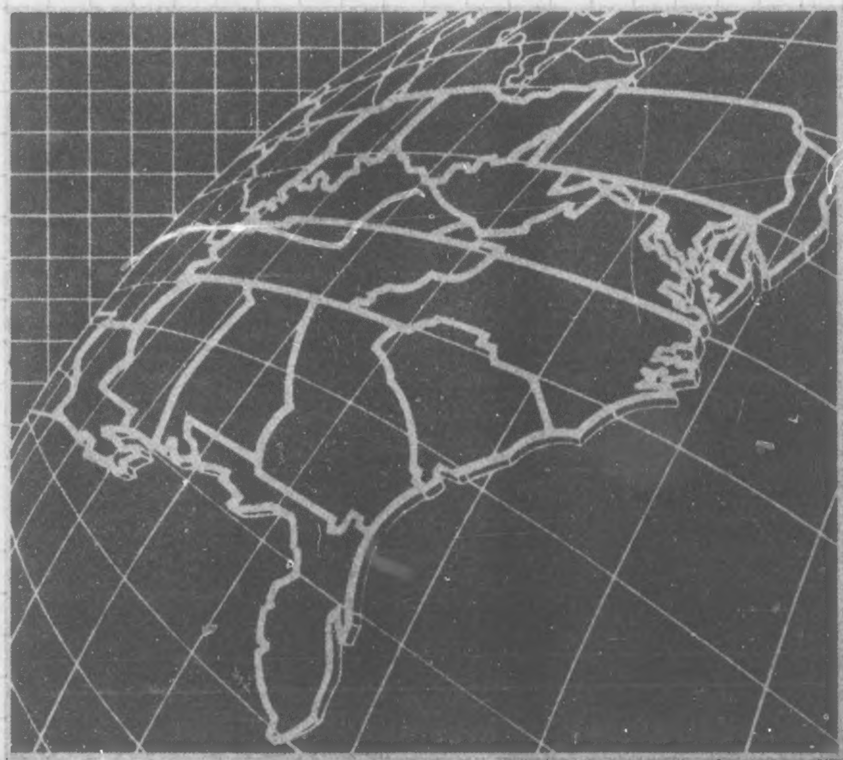


Organ sharing and more

The South-Eastern Organ Procurement Foundation (SEOPF) was founded in 1969 to coordinate the organ sharing activities among 9 medical centers in a 4-state area from Baltimore to Atlanta. Today, SEOPF is the nation's largest organ sharing program—a cooperative of approximately 40 medical centers covering nearly the entire eastern half of the United States.

The Foundation, a non-profit corporation, is owned by its member institutions, each of which appoints a trustee to serve on the Board of Directors.

The primary goal of the Foundation is to increase the quality and quantity of organs recovered, to meet the present and future needs of the transplanting community. In this effort, SEOPF works closely with government agencies, industry, and public and private organizations.



Foundation activities

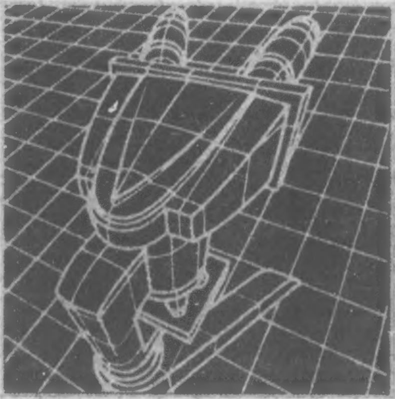
Standing committees of SEOPF recommend policies for Boa in the following areas:

Standardization and Quality Control

If organ sharing between centers is to succeed, there must be assurances that all members are equally capable of procuring, preserving, tissue typing, and transporting organs. Each cooperating institution must be certified in these areas prior to membership. High standards are maintained by annual workshops, continuous monitoring, and by the sharing of information and expertise.

Members work cooperatively to develop new, more efficient and cost effective procedures in all areas of organ procurement, recipient selection and transportation.

Meetings are held three times a year at different member institutions so that members can become more familiar with each institution's facilities and personnel. These meetings are open to all interested persons.

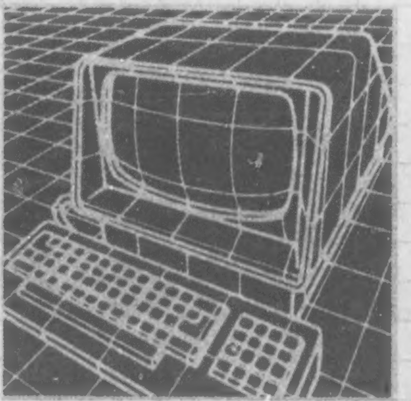


The UNITED NETWORK for ORGAN SHARING

SEOPF has been a pioneer in the development and implementation of computerized programs for the registration of potential organ recipients and donor-recipient matching.

Each SEOPF member has a terminal which links it to the central computer housed at SEOPF's headquarters. This terminal can be used to update the RECIPIENT REGISTRY at any time. Whenever a kidney becomes available, donor information is entered into the computer where the MATCH PROGRAM searches for suitable recipients, utilizing such factors as histocompatibility, patients' medical status, and geographic distribution of recipients.

In 1976, at the request of several non-SEOPF members, the Foundation released this computerized program for use by any transplant center wishing to utilize its services. The result was the creation of the United Network for Organ Sharing (UNOS). Today, UNOS serves as the registry and matching program for nearly the entire United States, with a recipient pool of over 5,000 patients.



rd approval and adoption. The committees oversee activities

The Kidney Center

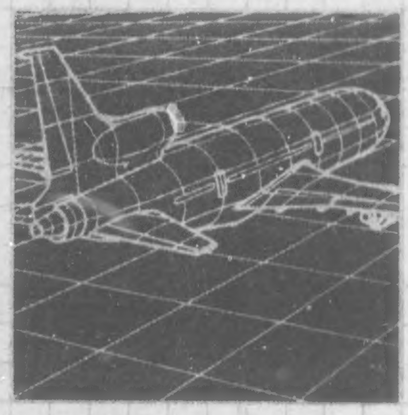
One half of all kidneys transplanted in the United States are shared between centers locally, regionally, and interregionally.

In July 1982, SEOPF created the Kidney Center. The goals of the Kidney Center are to:

- decrease the cost of transporting shared kidneys,
- decrease the discard rate of shared kidneys,
- increase the utilization of shared kidneys.

With headquarters in Richmond, Virginia, the Kidney Center is manned 24 hours a day, every day, to help transplant centers arrange for the most time effective and cost effective means of transporting kidneys.

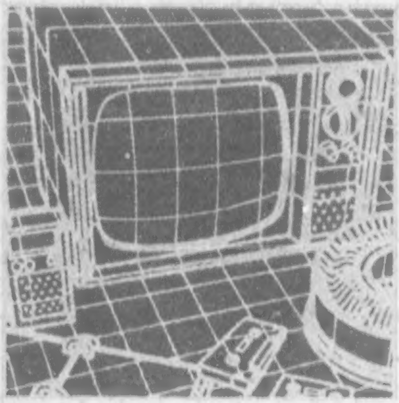
Utilizing the in-house computer system, the Kidney Center personnel can provide local transplant centers with backup and assist in the placement of organs.



Education

One of SEOPF's major roles has been in the area of education. The Foundation educates its members through an ongoing program of seminars and workshops. The Foundation also uses its pooled financial resources and expertise to create educational materials for the public, the professional community, and the transplant patient.

Each year SEOPF produces booklets, manuals, exhibits, radio, television and print advertising, films, and other audiovisual materials to increase awareness and understanding of organ donation and transplantation. SEOPF-developed media is currently being used by transplant programs throughout the United States and abroad.



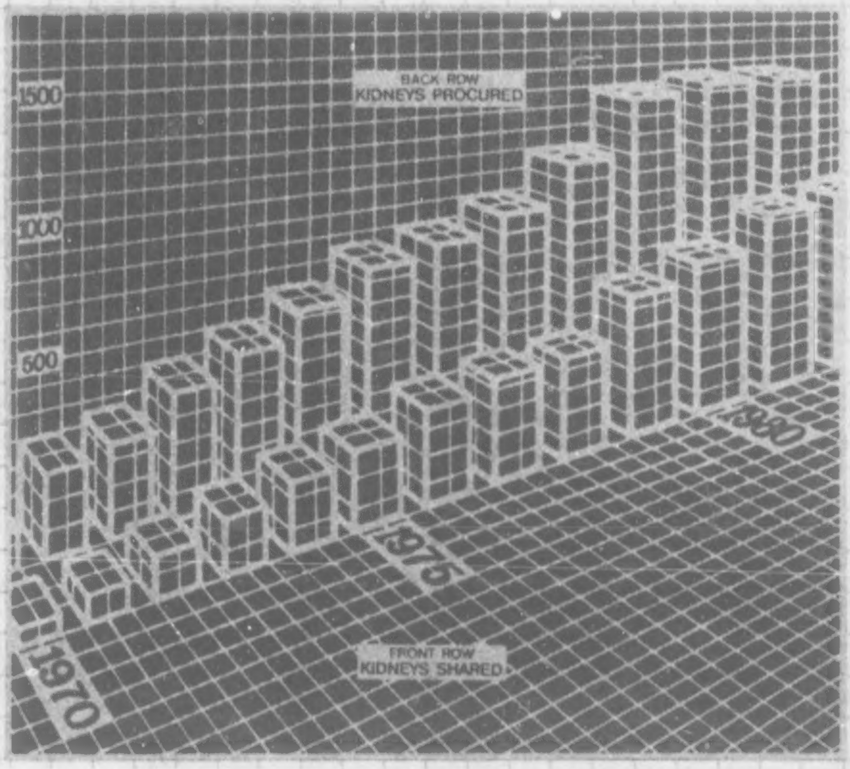
Foundation activities

Data Collection and Analysis

SEOPF's computerized system has provided its members with a powerful data base for retrospective and prospective studies of many factors which affect transplantation. This data base includes extensive information on all kidneys procured since 1977. Information derived from these studies is shared with the medical community through many papers published in leading scientific journals. The data is also used to improve the computer system, evaluate procedures, and recently, to develop predictive models for aiding in the selection of recipients.

Fiscal Management

In 1973 the federal government extended Medicare coverage to nearly all patients with End-Stage-Renal Disease to include the costs for dialysis and transplantation. Under the program, institutions procuring kidneys can be reimbursed for costs associated with the recovery process. SEOPF administers all billing for kidney acquisition charges when kidneys are shared by its members within or outside the SEOPF network.



South-Eastern Organ Procurement Foundation Member Institutions

Alabama

University of Alabama Medical Center, Birmingham

District of Columbia

Georgetown University Hospital, Washington

George Washington University Medical Center, Washington

Howard University, Washington

Army-Navy Transplant Service/Walter Reed Army Medical Center, Washington

Washington Hospital Center, Washington

Florida

Florida Hospital, Orlando

University of Miami School of Medicine/Miami Veterans Administration Hospital, Miami

University of Florida College of Medicine, Gainesville

University of South Florida/Tampa General Hospital, Tampa

Georgia

Atlanta Regional Nephrology Center/Grady Memorial Hospital, Atlanta

Medical College of Georgia, Augusta

Indiana

Indiana University Medical Center, Indianapolis

Methodist Hospital, Indianapolis

Kentucky

Jewish Hospital, Louisville

University of Kentucky, Lexington

Louisiana

Louisiana State University, Shreveport

Tulane Medical Center, New Orleans

Maryland

Baltimore City Hospital, Baltimore

The Johns Hopkins Hospital, Baltimore

University of Maryland Hospital, Baltimore

Mississippi

University of Mississippi Medical Center, Jackson

New Jersey

Newark Beth Israel Medical Center/New Jersey College of Medicine and Dentistry, Newark

Our Lady of Lourdes Hospital, Camden

Saint Barnabas Medical Center, Livingston

North Carolina

Bowman Gray School of Medicine, Winston-Salem

Charlotte Memorial Hospital and Medical Center, Charlotte

Duke University Medical Center, Durham

The North Carolina Memorial Hospital, Chapel Hill

Ohio

University of Cincinnati Medical Center, Cincinnati

Pennsylvania

University of Pittsburgh, Pittsburgh

Puerto Rico

San Juan Veterans Administration Hospital, San Juan

South Carolina

Medical University of South Carolina, Charleston

Tennessee

University of Tennessee, Memphis

Vanderbilt University/Nashville Veterans Administration Hospital, Nashville

Virginia

Medical Center Hospital/Eastern Virginia Medical School, Norfolk

University of Virginia Medical Center, Charlottesville

Virginia Commonwealth University, Medical College of Virginia/McGuire Veterans Administration Hospital, Richmond

Mr. **Gore**. Congresswoman Schneider, would you introduce our final witness?

Mrs. **Schneider**. I am more than happy to introduce Mr. Coleman, who is a constituent of mine, and I must say that I am very honored to introduce him to us today because he will tell us the true-life story of what was involved in having his best friend experience—have his child experience the need for a liver transplant and how he with a very cool, calm head reacted in a time of crisis.

I think this probably comes from his training as a policeman; how he organized as a citizen activist the solution toward solving this problem.

As I mentioned a little earlier today, because of his efforts and the efforts of many others, Justine Pinheiro is currently being operated on in Pittsburgh, and that is who Dr. Starzl was operating on last night.

So as we sit here we are hopeful that her condition will be on the upswing.

I might also mention that Justine's mother was most anxious to appear here today, but fortunately she is with her daughter. Also, there is in the audience a member of the board of directors for the Donor Alert Program that Mr. Coleman founded. His name is Al Skorupa.

I am delighted to have Mr. Coleman here today to tell us his story of frustration and success. Thank you.

Mr. **Coleman**. It was really short notice for me, as you probably know, and then with Monday, Justine getting notified—you will have to excuse my written testimony. I would like to read this to you.

My name is Raymond Coleman. I am a welding supervisor for General Dynamics, Electric Boat Division, and founding president of Donor Alert, Inc., a nonprofit organization founded in December 1982.

I became involved in organ procurement out of a desire to help a friend, Jose Pinheiro, whose daughter, Justine, hopefully not anymore, suffers from biliary atresia. This friend had been led to believe that if he made the public aware of his problem, he might increase his daughter's chances of getting a liver.

When he and I became frustrated in our efforts, I went to Mr. William Bennett, my general manager, for assistance. I felt that being a large corporation and dealing with the media they would know better than I how to approach the problem.

Not only did they lend their expertise to the problem of awareness, they agreed to pay for Justine's operation. Members of their staff worked tirelessly with me asking for no recognition and were happy with the thought that through their efforts they may help save lives.

This is the same reason that I am involved. All my efforts have been voluntary. I and the others involved receive no pay and have nothing to gain by my speaking here.

Our thoughts in starting Donor Alert were that if we went on a national scale by public awareness and education and establishing an 800 telephone number, and by using Justine and a representative of all people in need of transplant surgery, it would be possible to locate enough organs to reduce the waiting list, thus insuring Justine's survival and continuing the donor process.

Being an ex-policeman and having been involved in situations that met the criteria of potential donors, we decided to start our campaign with police departments. The criteria of being brain dead and on life support was not a normal condition of dying and the fact that auto accidents, violent crimes, child abuse and drug abuse was a major cause of this condition, made us believe that the police could be a big help.

We sent out on a national teletype a message that if they were involved in these situations, to please notify the hotline and we would notify local donor coordinators. Simultaneously with this message, ABC World News Tonight televised our efforts on national TV.

Since the inception of Donor Alert's 800 hot line on January 13, 1983, we have received over a thousand calls, have established chapters in six States, have registered hundreds of donors and have come to realize that besides the basic complexities of the area of procurement, it is frought with problems.

Some of the problems we as layman have encountered include: first, on the whole, the general public knows nothing of what is involved in organ transplants, what is necessary to become an organ donor, or how to become one, or what to do if they want to donate organs.

Second, although the entire organ donor procurement recipient transplant system is run, directed and controlled by medical professionals, and for the most part it should be, I have been told I have no right or business to be involved in organ procurement because we are layman.

Coordinators have advised me that there is such a delicate balance between them and the medical profession that a "bumbling, unprofessional might spoil" what they have achieved.

Our thoughts as bumbling unprofessionals is that if, instead of the almost secretive way they approached us, that they educate the people, that transplants affect most of the laymen. This way the medical aspects would not be a problem.

If a doctor was told by his patients that they accepted it and wished to be a donor, then if the opportunity to be a donor arose, the doctor, as a normal part of handling the situation, would offer this life-saving option to the next of kin.

This is not entirely the coordinator's fault. I have been told of cases of coordinators being called vultures and chased out of hospital rooms for their efforts. They have been accused of preying on the dead.

This exists probably because a doctor feels that his first duty is to his patient. With proper education of the public and the medical profession, it is hoped that once a person reaches a state of being legally brain dead, then again, as a normal consideration, a doctor would suggest or discuss the options and possibilities of lifesaving organ donations.

As you are aware, it appears that every State, in some cases, counties, cities, and regional areas, have organizations, some public, some private, some sponsored, involved in some sort of organ procurement.

These people work so hard in setting up their areas in different parts of procurement, such as eyes, kidneys, hearts and livers, that they feel it is their domain and seem to protect it with a vengence.

This not only occurs because of territorial protection, but extreme examples have been related to me of organs that have not been routed to an area because of personal conflicts.

When our national hot line was set up, it was in the hopes of coordinating these efforts. Professional or unprofessional, without the layman there would be no organs. With the tremendous advance in the medical procedures used in organ transplants and with the fantastic success that has been attained in liver transplants, I think that the time has come for a national computer network to be established which lists all patients awaiting transplants.

If this could be accomplished, then when a donor was located, the information could be fed into the computer and a match done making the selection impersonal and guaranteeing the most critical and best match would receive the organ.

This would make the information available to all medical personnel on a national basis. This should enhance the availabilitiy of organs and success rate even more.

If this is not done in an impartial manner, it could take years for all separate factions in organ procurement to become cohesive.

I have yet to talk to anyone involved in organ procurement who doesn't speak of his area in a protective way, and rightly so, because of the hard work necessary to develop it, but this attitude has to be shed now that organ transplants are growing at such a rapid rate.

Among the first calls we received on the hot line were people from NATCO and SEOPF. They stated that this was something that should have been done years ago.

NATCO stated that they would like to work with us on the hot line and invited us to Richmond, Va., to meet with members of their board. The discussions we had further strengthened my belief that a neutral party is needed if a national computer network was to be set up.

There is no room for any conflict when a human life is involved. One subject that all parties agreed on was that national programs of public awareness and education were necessary and the time had passed when they should have been implemented.

Following the establishment of our national hot line, several other organizations have established them. It was felt that a lot of money would be needed to accomplish this, so it would be something to work on in the future.

We felt that it could be accomplished now and we proved it. Granted, to be as effective as we should be, we still need funding, but if the Government never gave us a penny, we would still continue to grow because we are driven by a desire to help these beautiful children and will not be stopped by any obstacle.

If there is Federal money available, the Government should get behind an educational program that has already been established rather than putting money into duplicating the efforts of caring people who volunteer their time in an effort to help.

It is my understanding in some areas of transplant there is still a shortage of organs, but in liver transplants there are more organs than doctors to perform the surgery. Statistics show that the success rate in liver transplants has passed the trial and error stage and should be classified as a therapeutic and lifesaving procedure.

Without Government approval of this operation, hospitals and surgeons will not become involved and everyone's efforts will be in vain.

My final statement to you is our experience has shown that once people are made aware, they are willing to donate their organs in order that others may live. In our short existence we have acquired hundreds, approaching a thousand signed donor cards.

This has come about through what little exposure we were able to get. The next and probably greatest problem that exists with all cards and donors is that upon death, rarely is anyone sure of who they should call and, further, rarely does anyone check for donor cards.

A number of people who signed our donor cards were already carrying some sort of a local card, whether it was for kidneys, eyes, hearts, lungs or livers.

These people stated that they felt our national education efforts would enhance the chance of the card being looked for and an 800 number to call would enhance the availability of organs.

At one of our functions—a story was related to me of a woman's mother who before she died expressed a desire to donate her eyes so that another might see. Because no one knew who to call, the eyes were never donated.

Stories like this have been told to me time after time. It isn't just the man in the street who doesn't know what to do, this also extend to some doctors in hospitals. For example, on March 3, we received a call from a hospital in Colorado with a potential donor.

Luckily, they were aware of our 800 number and contacted us. We notified a donor coordinator, the liver was matched with a child in California.

What is needed is not 800 different 800 numbers, but 1 central 800 number that everyone is aware of and able to call for educational information or to either register as a donor or donate.

This would not infringe on the medical aspects of transplant or local and regional efforts, as a local coordinator would immediately be notified.

This concludes my remarks.

Mr. **Gore**. Now, let me get this straight. We have two different 800 numbers. Is that correct?

Mr. **Denny**. The 800 number established by the North American Transplant Coordinators Organization, 800-24-DONOR, has been established for the specific purpose, Chairman Gore, of providing information and referral services to physicians and nurses within the country.

It is staffed 24 hours a day by trained organ procurement professionals who are totally familiar with the identity of donors, the management of donor organ function, the psychological aspect of organ donation, the surgical recovery of the organs, and the network of regional programs throughout this Nation.

This 800 number, we hope, if made available to the physicians and nurses in the country, will enhance the opportunity for the recovery of organs.

We don't seek to compete with any other organization. We seek, however, to exercise our competence in terms of providing the health care professionals with the information that they need.

Mrs. SCHNEIDER. Would the chairman yield a moment?

Mr. GORE. Yes; delighted.

Mrs. SCHNEIDER. Is there any particular criteria—you refer to organ transplant professionals, is there some specific type of training or criteria that is followed in order to be acknowledged as a transplant professional?

Mr. DENNY. When I say transplant professionals, that is a generic term meaning the physicians, the surgeons, the transplant, or organ procurement coordinators. I think you refer especially to the organ procurement coordinators.

Mrs. SCHNEIDER. Yes.

Mr. DENNY. Those of us like myself who operate organ procurement programs and are available to do all of the necessary work in evaluating the donors and making the process work.

Mrs. SCHNEIDER. What I am trying to get at is whether or not we can see a new area of professionalism.

Mr. DENNY. There is a new area of competence——

Mrs. SCHNEIDER. Is there a recognized curriculum that one would take in going to school or the university or postgraduate studies?

Mr. DENNY. No; most organ procurement coordinators are either nurses or physician's assistants. Some of us are neither. Some of us have no background in medicine.

Mrs. SCHNEIDER. But are you certified? Is there a certification program?

Mr. DENNY. There is not yet a certification program, though I am sure that we will be moving in that direction. The North American Transplant Coordinators Organization does provide an intensive, annual educational program for organ procurement coordinators at the 110 programs in this country.

Mrs. SCHNEIDER. Thank you, Mr. Chairman.

Mr. GORE. Then, what differentiates you from Mr. Coleman is your experience at it?

Mr. DENNY. Knowledge, experience, and the fact that we are in the hospitals, that we are involved with the donors in the intensive care units, that we sit down and approach the grieving families to offer them the opportunity for life. His effort is, I think, primarily, and appropriately primarily designed to educate the public.

I have no quarrel with that at all. I think that it can be a valuable service.

Mr. GORE. Well, Mr. Coleman, you see it a little bit differently, don't you?

Mr. COLEMAN. First of all, I am not here to compete with the medical aspects of it. I bow to his expertise, as far as that is concerned.

My opinion is that my line can be just as—we both—I think both lines are needed. OK?

That he has done it this way, I don't think was very—how can I say it?—fair. If he would have let me know, I would have worked with him to make two different lines, one for general information and one for medical.

I would have referred all my calls. I have 35 calls on my desk of doctors, nurses, emergency room personnel that want to know what to do. If I knew that this was what they were doing, I would have just given them his 800 number and done it that way.

I think that there is room for both in this field. The general public needs, I think, the general public to tell it because they don't understand sometimes.

If somebody came up to me and said, will you donate your kidneys, I would say, no, I probably wouldn't. Right? But if somebody showed me why it was necessary, and if somebody showed me why it was necessary to donate my liver, then I sure would.

I carry a donor card, and I have been close to it, and I think if you put it to the people that way, people would understand and they would donate their organs, and there wouldn't be some of the problems that we have today.

Mr. **Denny**. May I mention something with regard to the NATCO 24-DONOR number?

Let me describe to you something in a hypothetical situation something of how the process works. A patient—this will be brief—a patient involved in an automobile accident, strikes his head against the windshield.

He is brought into the hospital. He is bleeding profusely. His blood pressure is dropping down to the danger level where his heart function is compromised.

His oxygenation is impaired because his breathing is slowing down. He needs to be put on a ventilator to support the oxygenation of his blood, to sustain the viability of the organs.

A doctor recognizes this patient as a probable victim of brain death. He is moving in that direction rapidly. It is a question of should the family be asked, should the family be approached, should they be offered the chance to think about donation?

He needs to talk with somebody immediately. Not only about should he talk with the family at that point, he needs to talk with somebody rapidly about what to do to sustain the vital organ function.

In dealing with victims of brain death, there are a number of physiological problems that occur that are not common to those of us who are living. Maintaining the organ function in somebody who is a victim of brain death is always a race against the clock.

It is always a competition between nature and those of us in transplantation whether or not the organs will be recovered in time. A physician who calls an 800 number needs to talk to a professional immediately who knows what to do to stabilize the blood pressure, to maintain the oxygenation, to assess when and how to talk with the family, to determine who is a suitable prospective donor.

He needs it rapidly. The fact that our 800 number, 800-24-DONOR, is manned by trained procurement professionals, is a vital service to the physicians and nurses in this country.

Mr. **Gore**. Well, I think I see the two points of view represented here. You just think that Mr. Coleman's group is not qualified to perform the function that you wish to perform.

Mr. **Denny**. Mr. Coleman and I have spoken over the phone about this on a number of occasions, and we had breakfast this morning together.

We concur in having the same shared sense of urgency. We concur in the sad realization that few of the available organs are, in fact, recovered.

Our concern, the professional organ procurement coordinator's concern is that the professionals be educated—I think Mr. Coleman's primary concern is that the Nation be educated, the public be educated.

Mr. **Gore**. And he faults the professionals for failing to do that.

Mr. **Denny**. Perhaps not without some justification. I think that we can do a better job. It is a question of money. I have 95 hospitals in a 150-mile radius of Pittsburgh to cover; approximately 15,000 beds. I don't know how many physicians and nurses.

Mr. **Gore**. Now, wait a second. You cover 90 hospitals in——

Mr. **Denny**. Ninety-five hospitals.

Mr. **Gore**. Ninety-five hospitals in a tri-state area around Pittsburgh.

Mr. **Denny**. Right.

Mr. **Gore**. Now, is there a feeling on the part of somebody in Texas, say, that if they plug into your network that is based in Pittsburgh, then facilities in Texas are going to be disadvantaged and patients in Texas are going to be disadvantaged relative to patients in the Pittsburgh area?

Mr. **Denny**. No; when I say our area, I mean the geographical area in which we are responsible for the education of the doctors and nurses surrounding Pittsburgh.

Mr. **Gore**. But you wear two hats; right?

Mr. **Denny**. The rest of the country is broken up into similar geographic areas. We wear the second hat in the sense that we share organs with other programs similar to ours.

Mr. **Gore**. Aren't some of those people that are wearing two hats in the rest of the country skeptical of your national group because it is collocated with your regional group?

Mr. **Denny**. No, sir, it is not collocated with our regional group. It is, in fact, at this time manned by the coordinators at the University of Pittsburgh.

Mr. **Gore**. They are both in Pittsburgh.

Mr. **Denny**. This function will be taken over within the coming 6 months by another group.

Let me explain, Congressman Gore. No; it is an information and referral service. If this hypothetical emergency room physician calls 800-24-DONOR, his burning, urgent questions will be answered, and then he will be immediately put in touch with the organ procurement professionals at his regional group.

If he is in Amarillo, Tex., we will put him in touch with the procurement people in San Antonio.

Mr. **Gore**. Maybe I heard you wrong, didn't you say in your testimony that there are 110 procurement groups around the country?

Mr. **Denny**. Yes, sir.

Mr. **Gore**. Didn't you say that only 50 of them will communicate——

Mr. **Denny**. No, sir, I alluded to the fact that the University of Pittsburgh has worked collaboratively with approximately 50 of these organ-procurement programs in recovering livers and hearts for transplantations.

Mr. **Gore**. I see. So, that was the other half.

Mr. **Denny**. We have worked with 50. There are another 60 that we have not worked with either because geography or time constaints prevent us from flying to the coast, for instance.

Mr. **Gore**. OK. So, you are wearing your local hat when you are talking about 50 other regions that you have cooperated with.

Mr. **Denny**. Yes, sir.

Mr. **Gore**. I see. Now, how many of the 110 procurement systems communicate regularly with your national organization, the North American——

Mr. **Denny**. Almost all of them. Almost all of them make use of the NATCO 24-Alert System. We have two systems. Don't get them confused.

The 24-Alert System is the recorded phone message system so that a procurement coordinator in Amarillo, Tex., can call and find out where a patient is who needs an organ from a donor similar to the one that is located in Amarillo. OK?

Mr. **Gore**. Yes.

Mr. **Denny**. That is the 24-Alert System. Almost everybody in the country uses that system to find suitable recipients for available, extra-renal organ donors.

For instance, the University of Arizona transplant team flew to El Paso, Tex., over this past weekend and recovered a heart because the procurement people in El Paso had called 24-Alert, learned that the University of Arizona was looking for a heart from a donor similar to the one they had.

They, in turn, called Arizona, and the two teams got together to recover the organs.

Mr. **Gore**. Dr. Pfaff, we have talked about these two 800 numbers, the two hotlines, and I understand the difference. Mr. Coleman, would you publicly recommend that a doctor call Mr. Denny's hotline and that public citizens interested in information call yours?

Mr. **Coleman**. Yes; if I had a call from a doctor, I would refer to a local coordinator in his area, anyway.

Mr. **Gore**. That number, again, it is really easy to remember, is 800-24-DONOR.

Mr. Coleman, what is your 800 number?

Mr. **Coleman**. 800-352-7001.

Mr. **Gore**. 800-352-7001; right?

Mr. **Coleman**. Yes.

Mr. **Gore**. Dr. Pfaff, in addition to there being these two numbers, there are, I understand, two computer registries; is that correct? One, the UNOS system, and the registry operated by Dr. Terasaki's group at UCLA; is that correct?

Dr. **Pfaff**. That is correct.

Mr. **Gore**. To what extent do these two computer registries overlap?

Dr. **Pfaff**. They do overlap.

Mr. **Gore**. They do?

Dr. **Pfaff**. Yes. UNOS membership and utilization is voluntary. All you have to do is buy a display terminal, pay your phone bill and pay for computer costs. In effect, it is the extension of the SEOPF's approach.

Mr. **Gore**. Wait a minute. The SEOPF?

Dr. **Pfaff**. South-East Organ Procurement Foundation. We will call it southeastern region. The southeastern region's technology just expanded nationally.

Dr. Terasaki has a very large tissue typing laboratory that serves almost all of the southern California programs. Much of their work is unified in his laboratory or by exchange with other laboratories that are generally located in the southwest.

There is no competition between the two. It can be complementary. My principal interest is in seeing the overall activities of our region perhaps adopted by other regions locally and then with inter-regional cooperation.

As you mentioned, we have our own 800 number, too.

Mr. **Gore**. You do?

Dr. **Pfaff**. I don't know what the number is. Basically it is for people to call in and sign donor cards. I don't think that there is any argument about a whole bunch of people doing some things that may overlap.

The biggest message we have heard today is that the public does not know, some professionals don't know or that they need to be reminded over and over again, and so that there is not—it shouldn't be thought of as competition.

I hope that there is a heck of a lot of supplementation. It took me a long time to learn how to read.

Mr. **Gore**. Unfortunately, it has taken a lot longer than that to get the awareness of the importance of organ donation.

Dr. **Pfaff**. We are doing a good job. For example, in our region—I will tell you, we are outstripping our use. That isn't the total matter, though. We are looking forward—and I agree with Mel, again, as to what should happen with transplantation.

I say it should double in terms of kidney transplants. You have heard that liver transplantation is going to increase in numbers. We are going from a number of roughly a hundred a year to more than that.

Cardiac transplantation is going from a hundred a year to more than that, so that we need to be looking towards the future. We need to modify our practices that we are using now. That is all. We need some help in doing that. I think many of the things that we have talked about we can do, the one that I can't do is to make sure that we are getting accurate information. You can really help us there.

Mr. **Gore**. There are, Mr. Denny, 35 children awaiting a liver transplant at Pittsburgh right now; is that correct?

Mr. **Denny**. Yes. Approximately.

Mr. **Gore**. How do you assign a priority as to which one of those children gets a liver that becomes available, assuming that several have tissue compatibility and the rest.

Mr. **Denny**. Let me explain one thing. In terms of liver transplantation, we do not look at tissue compatibility as we do in renal transplantation. That is why Mr. Coleman's suggestion that a nationwide computer system be established so that we could sort out suitability for an available liver on the basis of tissue typing is not practical.

Let me answer your question on two levels.

Mr. **Gore**. We have to sort it out on the basis of size, don't you?

Mr. **Denny**. Size and compatibility of blood type between donor and recipient.

Mr. **Gore**. I see. Let's suppose that you have several that have the same blood type compatibility and size compatibility, how do you assign priority?

Mr. **Denny**. If a donor is referred to the University of Pittsburgh and we have several people who are equally suitable for transplantation, the decision is left up to the physicians. Dr. Starzl and some of his colleagues make the decision based on the urgency of need.

All of these youngsters are going to die. Some, unhappily, will die before others, and they should be given the priority. That, in fact, is what is done.

Occasionally, we have to compromise. Occasionally, we have only an hour or two advance notice that a donor is available, and we may have a recipient who has an urgent need on the west coast 2,000 miles away, a slightly less urgent need recipient in Pittsburgh.

If we have only an hour or two to get that liver, we will have to, sometimes, select the less ill child. Generally speaking, all things being equal, we will pick the child, Dr. Starzl will pick the child, who is most desperately in need.

In the case of the 24-Alert System, again, the telephone service is available to organ procurement people to help them understand where there is a need for a liver or a heart that a donor in their area might provide.

On the 24-Alert System, if you call it, you will hear that the University of Pittsburgh, the University of Tennessee, Massachusetts General Hospital, Sacramento, Calif., Davis Medical Center are all looking for livers.

We prioritize the recipients in terms of the urgency of need. In other words, at the University of Tennessee for the last several days there has been recognized a very urgent need, what we call a priority one recipient.

That was the youngster that we saw this morning. This youngster is identified as a priority one recipient on the 24-Alert System, so that a calling coordinator, such as the coordinator in Virginia who called last night, is alerted to the fact that this need is perhaps more urgent than other needs for liver transplantation among children of the same size and blood type elsewhere in the country.

Mr. **Gore**. Very good. Let's suppose we could get hospitals to put up notice about the 800-24-DONOR number and for public information, your number, Mr. Coleman, that might be helpful, would it not? If emergency room physicians and critical care nurses and hospital administrators knew about this number, then they would—well, maybe it would make them think more often.

That is, I am sure, the intent of both of you, partly, in establishing such numbers.

Dr. **Pfaff**. Congressman Gore, actually I think that there is another solution. For example, if somebody from northern Florida were to call their number to find out that they should call us and get some help, we have done a bad job. So I think that you have got to pay heed to—literally hundreds of people are active in organ transplantation these days, and they are scouring those hospitals. If we aren't scouring them well, we haven't done a good job.

Have all of our programs done good jobs? No. Some are doing great and some aren't doing so great. We need to push ourselves a little more, too.

I should have made that point earlier. I don't think everything flows from a single source. Just as I differ with Don regarding making a potential recipient list available to donor hospitals in hard copy because that list is going to get awful lengthy.

Mr. DENNY. We don't differ on that.

Mr. GORE. Now, Mr. Denny, financial considerations enter into this priority. I guess you don't even get considered for priority typically unless the financial threshold has been crossed.

Mr. DENNY. The child has to be accepted for liver transplantation at that center providing——

Mr. GORE. The center typically turns down patients that don't have the ability to pay unless the mother can do what Mrs. Hall did and get a radio station and a lot of friends to help her raise the money from volunteer donations, poor people don't have the same chance, do they?

Mr. DENNY. It depends on what State the poor people live in. In some States medicaid has been helpful for those who are sufficiently indigent to allow them to qualify for medicaid.

Mr. GORE. In States where medicaid will not pay, then they are out of luck.

Mr. DENNY. Occasionally, families have been forced to turn to their communities for help. We have transplanted several patients in this group. Families having turned to their communities, having found the generosity of the neighbors, have recovered the funds through fundraising drives in their own areas and have been transplanted.

It does require that on occasion, yes.

Mr. GORE. Mr. Coleman, do you believe that the organ procurement effort in the country has been impaired by competition between different organ procurement systems?

Mr. COLEMAN. Yes. I have heard of different situations where that has happened. But, basically, I have to say this, they are hard working, dedicated people.

When they started in this, it was almost considered a macabre thing. But today people accept it and it is growing so fast that I do believe that these personal conflicts or if somebody is mad at somebody else or something this, should be removed somehow.

If it has to be forced upon them, removed. There shouldn't be any type of personal conflict in something like this when it involves a human life.

Mr. GORE. Mr. Coleman, I was looking at the list of organ procurement programs provided to us, and I notice that many cities around the country have more than one organ procurement system in the city, and some have as many as five different organ procurement systems or networks in the same city.

How does that work? Does that cause problems?

Mr. COLEMAN. Again, I just go by the personal talks. The medical people can tell you more on that.

Mr. GORE. Dr. Pfaff.

Dr. PFAFF. Really, no, it shouldn't cause problems. Are they competing for the same attention? Yes. How did this ever happen?

Organ procurement is an outgrowth of transplant programs, in the main. In some areas, people have seen advantage to coalescence. It is like anything else that a bunch of people do together.

There has to be not only a mesh of purpose, but very important, a mesh of personalities and some personalities don't get along with others.

Mr. GORE. Doesn't it make sense—I mean, if we have a situation where we have 110 different systems around the country, as many as 5 separate systems in the same city in some cases. We clearly see on the horizon a dramatic upsurge in the number of transplant procedures being performed and the demand for organs for transplant. It really makes sense to have a national strategy to, if not coalesce them all into a single system, at least devote a sufficient amount of attention to get rid of any competition that is impairing the procedures and make it a more sensible and rational system.

Dr. PFAFF. The competition doesn't impair the procedures. As a matter of fact, one of the major coalescences was just a dismal failure. That really isn't the matter.

It is really the question of effort, and the attention of a number of decisions that each of us make individually in terms of sharing organs and increasing production, of transplantation as a whole are all really scientific decisions in the end.

I think if all of us see the need for more organ procurement, we will do it. If, as people have heard today, there is a shortage of pediatric donors for a particular problem, biliary atresia, coordinators are going to pay attention to that.

Physicians are going to pay attention to it. Nurses are going to pay attention to it. They are going to hear it on the night news, I suppose.

Mr. GORE. Well, there is clearly a need for more organ procurement. I mean, there is not any doubt about that, is there?

Dr. PFAFF. Oh, I think in some areas there is doubt. In some areas, in some organs, I mean we are talking about now three liver programs in the country, ten cardiac programs.

Mr. GORE. We have got 35 children at this one hospital alone that are going to die if they don't get a liver. They are waiting for one now.

Dr. PFAFF. Thirty-five are waiting?

Mr. DENNY. Yes.

Dr. PFAFF. Are on the list?

Mr. DENNY. Yes.

Dr. PFAFF. That represents a very high proportion of probably the number of individuals in the country. I think that you need to understand that.

In other words, their need is for us nationally to provide organs to them.

Mr. GORE. Let me conclude 1 second. I am a little unclear about this. I am told that there can be expected to be as many as 4,000 people whose lives might be saved by a liver transplant in this country compared with 5,000 kidney transplants annually.

Mr. **Denny**. That is a projection based on epidemiological data. There are at least two problems in realizing the promise of liver transplantation. Certainly the first and foremost is funding, which we have heard today, and the second we have also heard today is the shortage of available organs.

Liver transplantation, you have to realize, until 2 years ago had results which did not recommend it as a therapy to be frequently applied.

It has only been within the past 2 years that liver transplantation has achieved the status that it has achieved. So we are talking about the future.

We are talking about something that is building dramatically. A year ago there was only one liver transplant program in the country. Then there were two. Then there were three. Now there are six.

By this time next year there will be another six. The number is growing rapidly.

Mr. **Gore**. Dr. Starzl said that as these regional centers develop and more patients are identified and we are able to treat more patients, that it would approach the level of 4,000 a year. I mean, that is a lot bigger than 35.

Dr. **Pfaff**. Yes.

Mr. **Gore**. So, clearly, there is a need for——

Dr. **Pfaff**. If it grows to that point and if that is the need and the number of individuals with hepatic failure, clear hepatic failure, and that is not just all the hepatic diseases and not all of the hepatic diseases that may result in death—I am getting overly technical, but if that were to happen, clearly we are going to need a good deal more donors, but the same is true for transplantation of each of the other organs that you have mentioned.

Mr. **Gore**. Thank you for your indulgence, Congresswoman Schneider.

Mrs. **Schneider**. Of course. You are the chairman, after all.

I must admit that after listening to the testimony by this particular panel, I am not at all convinced that despite the very dedicated efforts of keeping the public informed and providing a public service that it is as effective as it ought to be.

I guess to express that in more specific terms, I had asked my staff person here, Don Rheem, to go to the telephone and call the operator for 800 numbers and see what kind of information he could find.

I would like to relate to you the conversation that transpired. He called the operator and he said that "I have an organ to donate, and I would like the toll-free number, please."

She said, "May I have the agency name?" He said, "I have no agency name."

She then said, "Well, just a moment, I will give you the supervisor."

Well, essentially the supervisor went through the same thing and then putting on her thinking cap said, "Well, why don't you call your local hospital."

I am under the impression that if I were to call my local hospital now and ask for information on donating a particular organ, I would probably get nowhere.

It seems to me that there is a definite need to pursue the network of professional communications with the doctors and the nurses, but also the need for the public citizen information that would very clearly answer general questions such as if I wanted to donate my organ, who do I go to, where do I begin?

One of the things that I am concerned about is the regional aspects of the problem. I would certainly hope that when it is recognized that we have the interest of some very powerful professional groups and organizations, such as the AMA, and the American Hospital Association, we can get a great deal of public service work accomplished by groups like the American Heart Association, the Lung Association, and other citizens' associations that we ought to be able to solve this problem.

Now, my great concern is that, yes, here we are in a congressional hearing and so we always look for solutions that are derived from our jurisdiction, but it seems pretty clear to me that there is little we can do on this.

Now, I wonder is there agreement by this panel with me that there is nothing that we can specifically do?

Dr. **Pfaff**. My statement earlier was we had to do a hell of a lot of it. There are a few things you can do.

You can foster good information getting back to us about current success in dialysis and transplantation. That is a responsibility the Federal Government assumed and has not fulfilled.

So that is one thing that you can help us with.

Mrs. **Schneider**. Information generation.

Dr. **Pfaff**. Information. You must, I think, participate in the argument about funding for these other organs.

Mrs. **Schneider**. That is the next topic that I would like to discuss, is the funding.

Mr. **Denny**. Let me mention, again, I think, Congresswoman Schneider, that I think the Federal Government can do something that you as a Representative and your colleagues can do something.

The fact that medicare now funds 94 percent of the kidney transplants in this country and is ostensibly very eager to increase the number of patients transplanted, argues that medicare administratively should be in a position to implement c financial incentive system for those hospitals which generate donors of kidneys.

The Health Care Finance Administration is in a position to implement something like that without any legislative alteration in the Social Security Act.

On the other hand, they are not going to do it unless they get the pressure put on them to do it.

Dr. **Pfaff**. Are you suggesting a bonus system?

Mr. **Denny**. I am suggesting a financial incentive of some kind.

Mrs. **Schneider**. Such as a tax credit or a reduction in a medical bill?

Mr. **Denny**. For instance. I leave it to wiser minds than mine. But hospitals, you know, are heavily dependent upon medicare.

Medicare is heavily dependent upon the hospitals for the recovery of kidneys for transplantation, which is funded by the Government.

It only makes sense to me to move in a direction—the heart strings of the hospitals are closely tied to the purse strings of the hospitals.

Mr. **Gore**. Will my colleague yield?

Mrs. **Schneider**. Sure.

Mr. **Gore**. I would hope my colleague would wait until the end of the 3-day hearing to make the judgment that there is nothing we can do. I think already we have had a number of recommendations that could be included in a list of productive actions on the part of the Federal Government, not least among them, changing the procedures at CHAMPUS that deny approval of the transplant operations for children such as Captain Broderick's daughter.

In addition, I anticipate that we will have a list, a lengthy list of recommendations, many of them involving changes in Federal law, none of them as productive as or as important as the effort to increase the public's awareness of making organs available, but all of them helpful and all of them perhaps contributing to that larger effort.

Mrs. **Schneider**. Mr. Chairman, my question was specifically addressed to the 800 numbers, to the information exchange and the two separate networks, and I don't think that there is really anything that we can do on that score.

I would like to address the costs of the 800 numbers and the information exchanges that you do have. Mr. Denny, can you give us an idea?

We know now the breadth of your communications network. Can you give us an idea of the cost of that network?

Mr. **Denny**. Again, I have to differentiate between the two telephone systems that the North American Transplant Coordinators Organization has in place. The 24-Alert System, the recording system, which is updated two or three times a day to acquaint organ procurement professionals with the need for hearts and livers is a minimal cost.

It is not an 800 number. The caller, the organ procurement professional who is in the donor hospital has the burden of paying for that cost. That is not a problem. We all have credit cards. We just do it.

The cost of setting that up was less than $200. The cost of the 800 number that NATCO has established, annually will be—it depends on the times and charges—but we expect that it will run between $6,000 and $7,000 a year.

That is merely for three lines.

Mrs. **Schneider**. How about for the people who are operating those lines? I mean your overall information network, total cost, is about how much?

Mr. **Denny**. The indirect cost for the time of the organ procurement professionals?

Mrs. **Schneider**. Yes.

Mr. **Denny**. I have no handle on that. Again, our system has only been in place for 10 days.

Mrs. **Schneider**. That is true. Are volunteers right now manning those phones?

Mr. **Denny**. No, ma'am.

Mrs. **Schneider**. Paid professionals?

Mr. **Denny**. Professionals like myself, my colleagues, yes.

Mrs. **Schneider**. Mr. Coleman, can you give us an idea of some of the costs of your information network?

Mr. **Coleman**. The line costs us, again, depending on how much time is used, it averages $180 a month. We pay $30 a month for a 24-hour answering service. The line is manned 24 hours a day.

We pay $40 a month for an emergency beeper which I carry at all times. That is the cost of our line, about $250 a month.

We started this whole organization with a couple hundred dollars and a lot of effort.

Mrs. **Schneider**. All right. Terrific. I have no further questions, Mr. Chairman. Thank you.

Mr. **Gore**. Dr. Pfaff, what effect do you expect the new prospective payment reimbursement systems to have on the organization and function of organ procurement programs?

Dr. **Pfaff**. Gosh, I am not sure what diagnostic category they are going to use. There actually is quite a range in costs from institution to institution.

I can't tell you why. In some it is very high indirect cost. In university hospitals, they are having hard times. I think the efficiencies of different organizations varies rather substantially.

If everything would be to a unified cost, of course, it is going to cause so many more problems for us than if we lump transplant patients with people with bladder infections, there is going to be a substantial difference between those two if they hit the same diagnostic related group.

I would urge, frankly, that there be some greater uniformity, and yet the risk of creating it is to probably eliminate those groups that are a little more costly but that are still making a major contribution.

Mr. **Gore**. Well, some have expressed concern about the potential effect of the prospective reimbursement system on transplant procedures and organ procurement, in particular.

Dr. **Pfaff**. I would say it could have a chilling effect on those who are economically marginal but productive.

Mr. **Gore**. Yes. What about the business that Dr. Starzl raised, Mr. Denny, about the Aetna letter? This is the insurance carrier that is responsible for the Federal kidney program and apparently it sent a letter out to institutions participating that implied that their insurance coverage might be lost if they harvested extrarenal organs in addition to kidneys. Are you familiar with that?

Mr. **Denny**. Yes, sir.

Mr. **Gore**. Did that have a chilling effect?

Mr. **Denny**. I have no direct evidence that it did.

Mr. **Gore**. Dr. Pfaff?

Dr. **Pfaff**. Well, it creates an impediment. I guess, quite honestly, there is no way to measure because we don't have accurate data on the potential utilization of multiple donor organs and, you know, what is being done today.

In other words, our performance record isn't defined as yet. Further, there are a good number of programs that are just getting into multiple organ donations.

The bottom line is this. Actually, that Aetna did advise us that the cost that related to procurement of other than kidneys could not be attributed to the renal medicare program.

We have followed that, but have done it by a variety of means. We have participated in the harvesting of both livers and hearts and have a very active program in terms of joints that we are doing with the orthopedic groups up and down the east coast.

In many instances we have some sources of funds. Truthfully, in dealing with the University of Pittsburgh our costs that particularly related to liver removal for the purposes of transplantation were then passed back to Pittsburgh.

Heart donor costs were segregated to the point that we could and then were sent to the recipient institution. I don't know what the payment rate has been, but I suspect after all the conversation that I have heard these last several days that, indeed, because dollars are such an impediment to individuals who require that kind of management, that one of the first things that the recipient institution has been paying attention to is, indeed, the donor institutions.

Mr. Denny. I think that we have to be careful and not imply that Aetna is at fault for this. Aetna is merely operating under the guidelines established by the Health Care Finance Administration following the legislation which was enacted in 1973 and subsequently.

Aetna is responsible as the intermediary between HCFA and the independent organ procurement programs to see to it that the regulations governing the financial aspects of organ procurement are adhered to.

Their statement to us that we would not be covered by medicare in the event of malpractice, for instance, and a court case involving malpractice surrounding organ procurement came also with the recommendation that we take out insurance on malpractice liability for extra-renal organ procurement.

That is, in fact, what we did do.

Mr. Gore. In other words, it emanated from the Health Care Financing Administration through Aetna?

Mr. Denny. Yes. Aetna is merely the intermediary.

Mr. Gore. We are going to have the Health Care Financing Administration on the third day of these hearings along with the Surgeon General. We will be exploring a lot of these reimbursement questions at that time.

A couple of other real brief questions. It seems as if—and I know this is a delicate area—it seems often desirable to maintain a potential donor on life support after brain death has occurred; is that correct, Dr. Pfaff?

Dr. Pfaff. That it is desirable? It is for the purposes of multiple organ removal in that, let's say, if somebody is coming from a heart transplanting hospital to our institution, it might have a delaying factor, usually in a mattter of hours, not more than that.

Mr. Gore. But you don't get into a conflict on who pays for the cost of care under those circumstances?

Dr. Pfaff. No. No. Well, for the purpose of the kidney donor, from the time of the diagnosis of death, the renal medicare program assumes the cost of continued care. But that is not for long because these are unstable individuals in many instances. We are anxious to proceed.

Mr. **Gore**. But if the extra care is principally needed for the multiple organ——

Dr. **Pfaff**. We are still talking about hours.

Mr. **Gore**. But is it charged to the kidney program?

Dr. **Pfaff**. Quite honestly, I am not sure. I could imagine that potentially being a point of confusion at the time and to the billing personnel. I would guess that the receiving institution would assume at least part of those costs or the fair share of costs.

Mr. **Denny**. Yes, sir. That, in fact, is what happens. We regularly pay for a liver anywhere between $1,000 and $3,000, sometimes as high as $4,000 of the share of the donor-related charges, the balance being picked up by the renal programs.

Mr. **Gore**. Let me note that in tomorrow's hearing we are going to lead off with the perspective beneficiaries and voluntary agencies, including Charles and Marilyn Fiske, the parents of Jamie Fiske, who will also be with us tomorrow.

In the second panel we are going to explore indepth the bioethical considerations with a number of bioethicists, including the Executive Director of the Presidential Commission on Bioethics.

Then we are going to look in the third panel closely at the legal considerations, and you got into this a little bit in your testimony, Mr. Denny, and I would say for the record to my colleague from Illinois that the counsel for the National Conference of Commissioners on Uniform State Laws will be among the witnesses on that third panel.

Then the third day of the hearings will be a little later on, but I wanted to close by thanking members of this panel particularly for your contribution here today, and to all of the witnesses who have helped us in this first day of the hearings, I want to express our thanks and appreciation and with that, the hearing will stand adjourned.

Dr. **Pfaff**. Thank you.

[Whereupon, at 2:45 p.m. the hearing was adjourned, to be reconvened the following day, Thursday, April 14, 1983, at 9:30 a.m.]

ORGAN TRANSPLANTS

THURSDAY, APRIL 14, 1983

House of Representatives,
Committee on Science and Technology,
Subcommittee on Investigations and Oversight,
Washington, D.C.

The subcommittee met, pursuant to other business, at 9:35 a.m., in room 2325, Rayburn House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Mr. Gore. The subcommittee will come to order.

I would like to welcome all of our witnesses and guests for the second day of these 3 days of hearings on organ transplants.

Yesterday was both moving and disturbing. We were all excited and filled with joy to hear about Brandon Hall receiving a liver for transplantation. The latest reports from Memphis are that he is doing fine. As all patients after such surgery, he is in a critical condition but is doing quite well. We are all very optimistic and prayerful for his speedy recovery.

Yesterday's hearing also had some very disturbing testimony, however. The testimony from Captain Broderick, as well as others, told of people who may die, children who may die, not because the necessary medical technology is unavailable, nor because a transplantable organ is unavailable in some cases, but solely because the patient cannot pay for the procedures.

The third-party payers don't pay for such transplant surgery, either. In fact, I found it to be quite shocking that the U.S. Government would not take care of active-duty members of the U.S. Army and the other services by providing for transplants for family members because, in the judgment of the Department of Defense, it was too expensive.

I think that policy has to be changed. Without objection, the subcommittee will proceed with the plan that we discussed yesterday, to contact the Department of Defense and the appropriate agency within the Department of Defense, to ask for an immediate change in that policy.

We also learned yesterday that transplant surgery is at the dawn of a brand new era. In part, this is because of the advent of a marvelous new drug, cyclosporin, which holds great promise as a means of selectively preventing rejection of transplanted organs by the body's immune system.

It also has a great deal to do with the increasing skill and knowledge in the medical community, of course. However, we also learned that we are not likely to have sufficient organs to meet the demands generated by these impressive advances in medical technology.

Nothing better illustrates what we are here for today, though, than our first panel of witnesses. It includes little Jamie Fiske and her parents, who, more than any single case, have come to symbolize the hopes and the despair of many American families who have children like Jamie, who were born with incurable liver disease.

It is estimated that 1 in 20,000 children are born with Jamie's condition, biliary atresia, a condition in which the liver lacks the ability to excrete waste products. Two of these children were with us at yesterday's hearing.

In fact, I say two, two were at the witness table, but there were others in the audience who came with their parents after learning about the hearing, and I believe there are some others in the hearing room today. We welcome you and hope these hearings will be of some benefit in the effort to find a solution to the problems that you are experiencing. For most of these children, only a liver transplant offers any prospect of survival beyond infancy.

Jamie's father, who is with us, felt compelled to mount a national media-assisted campaign to secure a liver for his daughter. As is quite evident, he succeeded, and Jamie was successfully transplanted at the University of Minnesota in November, but only after the Fiske family had hurdled a series of heart-rendering obstacles, which they will describe for us this morning.

We will also hear from Michele Jones, who is the niece of our ranking Republican, Mr. Skeen. I am going to call upon him to introduce the Jones family in a moment. Michele received a kidney transplant in February, after spending more than 2 years on dialysis.

Representatives from the National Kidney Foundation and the American Liver Foundation will relate their efforts on behalf of waiting and past recipients.

The balance of the morning will be devoted to a careful analysis of the bioethical and legal issues surrounding organ donation and procurement.

How can we best satisfy the moral imperative to secure transplant organs for victims of incurable disease while safeguarding the rights and privileges of prospective donors and their families? To help us, we have some of the most eminent bioethicists and authorities in this area.

I hope we can conclude our day feeling that we have taken steps toward understanding and removing some of the obstacles from the path of the next Jamie Fiske.

Before calling on Congressman Moakley to introduce our first witnesses, it is an honor to recognize the distinguished ranking member of the subcommittee, Mr. Skeen.

Mr. SKEEN. Thank you very much, Mr. Chairman.

I concur in the points that you have made in your statement, particularly in regard to the fact that it is time for us in Government to change the policies to suit the new and advanced degree of technology afforded us today in common medical practice in the United States. It is now a practice, it is not experimental, and it is time for us to tell the insurance carriers, as well as the Federal

Government, that this change has been made and that they should react accordingly.

I want to particularly thank you for the courtesies and the consideration that you and the members of the staff, both majority and minority, have shown the recipients and other witnesses that have been here today. It has been outstanding, you are to be commended, and I wanted to take a little time to do just exactly that.

I don't want to spend a lot of time on a statement, but I would like to have the personal privilege, first of all, of introducing my wife, who is here accompanying my niece, Michele; the gal who does the most work keeping me up here and running the best ranch in New Mexico. I would like for her to stand up, if she would, please. Thank you.

It is a privilege to have Michele here. It has been 2 months since her operation. We have tracked this problem through her lifetime. I did not know that she was a recipient until she had actually been in the hospital and the transplant had been made. It happened that quickly.

I just want to say to you folks who work in this area, you are to be commended because it has been a labor of life. For one who has lost a member of his family because there was nothing that could be done at that time, I want to say to you that we have come a long way. All of you are to be commended, and you have my heartfelt thanks for all the things that you do above and beyond what your job calls for. It is your hearts that are involved in this process, and I appreciate it very much.

Thank you, Mr. Chairman.

Mr. **Gore**. To introduce our first witnesses, I am pleased to call upon our distinguished colleague, Congressman Joe Moakley.

STATEMENT OF HON. JOE MOAKLEY, A REPRESENTATIVE IN THE CONGRESS FROM THE STATE OF MASSACHUSETTS

Mr. **Moakley**. Thank you very much, Mr. Chairman, members of the committee.

The plight of little Jamie Fiske became known throughout this Nation last fall when her parents went before the American Pediatrics Association conference to appeal for assistance in locating a very critically needed liver donor for Jamie.

Without the national attention received because of this unusual request, Jamie may not have been lucky enough to locate a donor in time to save her life. Fortunately, however, Mr. Chairman, with the help of the medical community, the national coverage given to her plight, and the dedication of her parents, a compatible donor organ was found and successfully transplanted by a team of very skilled surgeons.

To look at this healthy, happy little girl today one would not be able to tell that just a few months ago her young life was in such grave danger. Jamie Fiske, Mr. Chairman, I think is the best example of the hope that exists through this extraordinary surgical procedure and also of the immense need for a nationwide network to match organ donors with those individuals who are in desperate need of transplants.

Mr. Chairman, I am very honored and very proud to present to this committee Charles and Marilyn Fiske and, of course, their very healthy daughter, Jamie.

Mr. GORE. Thank you, Congressman Moakley.

Charles Fiske, if you wish to begin, we are delighted to hear from you. Please move one of those microphones over where we can hear you better.

Mr. FISKE. Can you hear me?

Mr. GORE. We can hear fine, and if Jamie wants to squeal into that other microphone, that will be just fine, too.

STATEMENTS OF CHARLES AND MARILYN FISKE, AND DAUGHTER JAMIE, LIVER TRANSPLANT PATIENT; MICHELE JONES, KIDNEY TRANSPLANT RECIPIENT; DAVID OGDEN, M.D., PROFESSOR OF MEDICINE, CHIEF, RENAL SECTION, UNIVERSITY OF ARIZONA HEALTH SCIENCE CENTER; AND THELMA KING THIEL, VICE CHAIRMAN AND EXECUTIVE DIRECTOR, AMERICAN LIVER FOUNDATION

Mr. FISKE. Good morning, Mr. Chairman, and members of the committee. We thank you for inviting us here this morning.

We would like to introduce ourselves. I am Charlie Fiske, this is Marilyn, this is Jamie, and somewhere in this room is Daren, our 3-year-old son.

We would like to take a look at three issues that we faced as a family. The first and the most pressing issue was the fact that Jamie's health was declining. We were told that she had a rare liver condition and unless she had a transplant within a very short space of time, she would die.

We felt she was in a fine medical facility at the University Hospital in Minnesota, receiving excellent care under Dr. Sharp and Dr. Freese and a nursing staff and Dr. Najarian and Dr. Ascher, but there was nothing they could do except wait for a donor organ to be identified.

The second issue we faced was the whole issue of funding. The problem became very apparent when we had gone to our insurance company, Blue Cross-Blue Shield, and they had put in writing that they would cover the cost of the surgery. Then they notified the hospital, after we had received three letters saying they would cover it, that they wouldn't cover it. Going back to Blue Cross-Blue Shield to get clarification, the best they could offer us would be to work out something privately.

At that point, because of the cost of that, we turned around and went back and sat down with different folks, predominantly a fellow named Kent Jones from the local Brockton Enterprise, who had followed Jamie's story as a human interest story in the area we live in. We went through the whole story with him.

We were able to get a hold of the speaker of the house, Mr. Tom McGee, and explained our situation to him. He told us very carefully he would approach Blue Cross-Blue Shield and straighten it out. We also went to one of the news stations in the Boston area, channel 7, and spoke with a Mr. Tom Ellis, who took the information.

Through those three men, within 24 hours, Blue Cross-Blue Shield had decided that they would cover the entire cost of Jamie's medical care.

That same day, on September 29, Jamie was put on the transplant list in Minnesota. On top of that, the then Governor of Massachusetts, Governor King, approved medicaid approval for Jamie for the surgery, which came through October 29.

So, those two issues—the one, the issue of declining health, which we had no control over, and the funding issue—were behind us, through Blue Cross-Blue Shield assuming costs for that, as well as medicaid willingness to back it up.

The third issue that we faced was the issue of donor awareness. The day that Jamie was put on the transplant list in Minnesota, we were told that her vital signs, her liver size, her blood type, would be put on a computerized network which would go out to the midwestern and the western States, if a donor became available.

On top of that taking place, both the formal network that was set up, individual doctors at the hospital, who had become very attached to Jamie, contacted their classmates, asking them just to be aware of the possibility of a donor being identified. So, both on the formal and the informal level, we knew that word was going out.

The difficulty became between September 29 and the date of the operation, November 5. There was that whole waiting period where Jamie's health, we were told, was declining very rapidly. We could tell from the size of her stomach, from her color, and from the periodic episodes of internal bleeding that she really didn't have much time at all.

During that period of time I was in Boston and Marilyn was in Minnesota, taking care of Jamie on a daily basis and watching her die. Through no fault of the medical facility there, because they were giving her excellent care, the thing that Jamie clearly needed was to have a donor identified and liver implanted in Jamie.

We didn't feel it was enough to go through the normal channels. We knew that her protocol was on the computerized network. At that point we went to the New England Organ Bank, and through the dean of the medical school at BU, Dr. Sandson, put me in touch with Dr. LoGerfo, who wrote to Dr. Najarian. Dr. Najarian, from Minnesota, wrote back and said that if a donor was identified in the New England area, the team would fly out from Minnesota to Boston to identify that liver.

With that done, we—myself and Marilyn—took a look at which direction we could go in. We do know that her name was on the computer. We could call up that computer and hear again her statistics mentioned on that computer.

We contacted the AMA in Washington. They said that we should get in touch with the American Academy of Pediatrics in Chicago, which we did. We called them, specifically looking for the mailing list of their 500 pediatric surgeons.

The organization represents about 24,000 pediatricians, and we felt that 500 of those people being surgeons, predominantly neurosurgeons, would probably see a brain-dead child. What we were hoping was that by that list, we could personally write letters to those particular 500 surgeons.

As it turned out, their national convention was taking place at exactly the same time, in New York City. We asked if we could address that convention in New York City. There was a lot of hesitancy from the academy, and I think rightly so, because it was their convention and I was not a doctor.

Again, we went back to them and said that our problem was symbolic of a lot of other children needing help, not only with livers but with other organs. The response that we got back was well, we will think about it, et cetera. We were not getting a clear answer back.

So, with that, we turned around and went back to the same people in the media who had followed Jamie through the Blue Cross-Blue Shield incident. At that point, we went to other media both within the Boston area and also through the national networks—ABC, NBC, and CBS—and just presented the problem that we had, that we were not getting a clear answer back from the academy.

On top of that, we sat down and looked at probably people that could help us. We went, first of all, to Congressman Moakley's office and asked if he could ask the academy for us. Very clearly a response out of Congressman Moakley's office was yes, we will call to see if we can get a clear answer.

The then Lieutenant Governor of Massachusetts, young Tom O'Neill, clearly became involved in it. Senator Kennedy's office, we asked them the same thing. Very clearly Senator Kennedy's office responded. Senator Tsongas' office very clearly responded, asking that same question. The Speaker of the House, Mr. O'Neill, very clearly asked the academy, can this family get up in front of you.

Through a media awareness and political support, there was a clear decision made back to allow us to speak to the academy. The address was on the last Thursday of October, October 28. Our appeal was basically for Jamie, and also mindful of the fact that not only we were waiting, but many other children like her were waiting.

A young family in Utah was sitting watching television that very same night, on that Thursday night. They had two children, both about a month apart from the ages of our children. Their young son, Jess, was involved in a car accident the following Tuesday.

The family remembered that national telecast that had taken place the previous Thursday. They had approached their doctors and asked if it was possible that the liver of their son, Jess, if it was compatible, there was a family, they did remember, that had gotten up the previous Thursday.

Phone calls went from Utah to Pittsburgh. Pittsburgh identified that there wasn't a candidate there that could benefit from it, simply because they had done a number of operations that week.

The call then went from Pittsburgh to Minnesota, Minnesota clearly responded, and went to Utah and retrieved the organ, the liver of Jess Bellon. On November 5, Jamie received a new liver.

What I would like to do—we only have one copy of this, but we will submit it for the record. It is pictures that very clearly demonstrate the before-and-after effects of what happened from before November 5 and what happened afterward.

Actually, the best example of a healthy operation and a successful transplant situation is Jamie right now. When she left the hospital, she was 14 pounds in December, and she is now 24¾ pounds, doing very well, and doing some of the things she couldn't do when she was so sick.

The reason for presenting all of that is that there were a number of people involved in Jamie's situation, numbers of media people, numbers of political people, numbers of residents of Massachusetts, numbers of residents of Minnesota, who became directly involved in it through telephone calling and asking and being aware.

As a result of that kind of effort, a number of things happened that we have outlined as results. One is that right after the operation the donor family, through their social worker, Jayne Taylor, asked if we would get in touch with them. The donor family had initiated that process because they had heard that national telecast.

We talked with them the following Tuesday and Wednesday. Most of their conversation was spent asking how Jamie was doing. We have had contact with them, and we feel that the Bellons of Utah are Jamie's extended family and they share in Jamie's good health as much as we do. They did it at one point in time, what no other family in the United States was able to do it; that is, offer Jamie an opportunity to live.

Beyond that, what has happened is that individual families have called us. We could go through a list of names, everywhere from California to Mississippi, even to the Hall family that we had planned on meeting here today. Our feeling was hopefully we don't meet you here for the right reasons. It was so good to see that take place yesterday, with that transplant.

Individual families have contacted us. Strangely enough, it has not just been families of liver patients. It has been families who need corneas, who need bone marrow transplants, who need kidneys, who need other organs for transplant.

So, some of the same situations that we faced in terms of Jamie's declining health, other families are going right now through that same experience. We have had that kind of ongoing contact with families, if for no other reason than to say it does work, there is a possibility of hope.

On the State level in Massachusetts, the Governor of Massachusetts, Michael Dukakis, proclaimed March as Organ Donor Awareness Month. We are told that on the national level there is an effort to declare one of the months or one of the weeks as Organ Donor Awareness Week.

Also, in Massachusetts the AMVETS, who are traditionally involved with blood drives, became aware of Jamie's situation. They set up on March 29 an organ donor awareness drive in conjunction with their blood drive. Involved in that group were all the organ banks in New England.

It is interesting because the McKeon post in Dorchester is the largest AMVET post in the country. The State commander, Robert Medairos, became involved with it and is taking that project, organ donor awareness, to the national level at his national convention, which is coming up I want to say in Florida within the next 2 months. He is taking that on as a project that AMVETS nationally can get involved with, much like their blood drive.

It is very encouraging because that group has connections across the country, and their willingness to do that as a volunteer organization has an impact for people not only waiting for livers, but for other organs as well.

Finally, one of the results that has happened is there has been an ongoing contact that we have had with the White House. During the ordeal with Jamie, the President had written to us twice, one a letter to us commenting on the fact that the Bellon family did a caring and generous thing in terms of the gift of their son's liver to Jamie, and also gave best wishes to Jamie. Also, the President had taken the time to write Jamie a short note at Christmastime, a "Dear Jamie" letter.

Since that time we have had an ongoing contact with the White House. They have asked us to call other families, again not only families of liver transplant patients, but bone marrow transplantations and kidney people. That kind of behind the scenes thing has been taking place.

We raise all that because the issue for us is certainly not partisan. We have got local politicians involved in it, both sides of the aisle, on the congressional level, on the senatorial level, at the White House level. It hasn't been a partisan type of issue, it has been an issue about caring for people, people caring for people.

So, it has been very encouraging, when you get various phone calls, and it doesn't really make any difference which way I voted or whether Jamie is whatever, a Democrat, Republican or Independent. The fact is she needed life.

That kind of support has presented us with some of the deficiencies in the system, the three problems we faced. One, the declining health, we had no control over. The issue of funding, there is input into that. In Massachusetts, Blue Cross-Blue Shield did pay for it, as well as Massachusetts medicaid.

The overriding problem is donor awareness. Why is it that we had to go as a family to some of the lengths we did to involve all levels of government, all levels in contact with media, phone bills that were exorbitant, just to get word out, to have a family that lives in Alpine, Utah, watching TV, not knowing where Bridgewater, Mass. is, and responding accordingly? Fortunately, that gift of life saved our daughter.

What we feel needs to take place, again based on our experience. One is that there has to be a centralized type of organ donor awareness institute or program, both on the regional and on the national level. The way that would be set up would be that in each one of the regions the specific responsibility of that program would be organ donor awareness and public education.

The problem is that the local organ banks—and we have run this by the New England Organ Bank, the Eye Bank, the Kidney Foundation of Massachusetts, and the Massachusetts General Hospital Bone Bank—don't have the ability to do public awareness. It is not a reimbursable cost.

We presented the idea of them, with a separate organization, doing organ donor awareness, and they bought it wholeheartedly. They thought it was a good thing that they could match up with.

To put some teeth into it, what would be needed would be that any hospital receiving federal money or clinic, that they institute an organ donor awareness program within their hospital, not something very costly at all, but that they raise the issue on the hospital level.

Second, that every single medical school that receives federal funding of any sort be required to institute organ donor awareness seminars as a course of study within their medical school.

Third, any group that is receiving law enforcement money on the federal level or on the local level, that in their police academies, there be training officers to be aware to look on a driver's license for the symbol of universal donor on the person's license.

We would encourage that to take place, again because organ banks are not in the business of public awareness. That is the big problem that we faced, is getting word out. We had to go through political people, we had to go through media people to get word out. If there was something, again, at the regional and national level to do that. Then, I think the problem that we faced, the greatest one we would be able to look at, would be her health. Other organizations, like the AMVETS, have picked that up and are willing to take it forward.

I think by that kind of effort the feeling of waiting, the feeling of hopelessness that we went through as a family, at least there would be something that we could say is in place.

The other issue that comes up, of course, is the issue of matching up proper donors with proper recipients. That is a whole communications system that needs to be put in place, so that the proper donor gets matched up on a needs basis. The awareness issue is the one that we clearly have been faced with.

Marilyn, do you have anything to say?

Mrs. FISKE. I think mainly, just over the past months, that Charlie have shared everything that we have spoken about today. It just involves very much the heart that has gone into this.

I think over the past months it is very difficult to share some of the emotional kind of ends, the pressures and the strain, but in fact it is not necessary today because we are just so elated and thrilled to have Jamie home with us and to watch she and her brother in action together at home.

It is the dreams, maternally and paternally, that Charlie and I had when we were expecting Jamie and had to suppress them because there were so many medical priorities that took over. All of a sudden we could feel ourselves starting to unwind and starting to dream the thoughts and the hopes that we had as a family.

Since the past few months, in Minnesota, we have seen too much, and we have been someplace, that we feel compelled, that we have to be able to help other little children, help the adults that we met in Minnesota.

I think, along with Charlie, our main goal and our hopes would be to set up some kind of a national awareness program just to alleviate the strain, the additional strain that families have to go through.

Our hearts and hopes are with the parents in this room of children and the adults that may be in this room also, who are going through similar kinds of ordeals. We also have such a hope in our hearts for all of them, and we certainly hope and thank you for inviting us here, to be able to see something come from this.

Thank you.

[The following material was submitted for the record:]

TESTIMONY FISKE FAMILY

Committee on Science and Technology

Sub-Committee on Investigation and Oversight

April 14, 1983 9:30 AM Rayburn Office Building Rm. 2325

OUTLINE

1. Review of Jamie Fiske's health condition.
2. Medical steps taken by University Hospital, University of Minnesota both formal and informal.
   Medical support of effort to identify potential donor for Jamie.
3. Waiting period between time of placement on transplant list and surgery. Personal reflections and deficiencies in system.
4. Steps taken to involve New England Organ Bank, American Academy of Pediatrics, political support and media awareness.
5. National alert through American Acedemy of Pediatric's convention and the response of the Bellon family of Utah.
6. Results:
   - a. Contact with donor family.
   - b. Problem of organ donor awareness through nationwide contact with individuals needing transplant surgery.
   - c. Donor awareness Proclamations on State and Federal level.
   - d. John P. McKeon Post No.146 Amvets - Organ Donor Awareness Drive, local, State and National impact.
   - e. White House response.

Recommendations: To be presented at testimony on the 14th of April

JAMIE FISKE SPRING 1982

OCTOBER 1982

2 weeks before transplant operation, November 5, 1982

JANUARY 1983

John P. McKeon Post No. 146 Amvets

BLOOD DRIVE & ORGAN DONOR AWARENESS DRIVE

MARCH 29, 1983 3:00PM to 8:00PM

The Address Ceremony will be held between 3 & 4PM.

On this day the John P. McKeon Post #146 Amvets will conduct its annual Blood Drive coordinated by the American Red Cross. In response to Governor Dukakis's Proclamation of March as Organ Donor Month, the Post on this same date will conduct an Organ Donor Awareness Drive. The following groups and individuals have wholeheartedly agreed to participate with the Post in this drive.

New England Organ Bank
New England Eye Bank
MGH Bone Bank
Shriners Burns Institute
Skin Bank
Jamie Fiske, Liver Transplant Recipient
National Kidney Foundation of Mass.
New England Renal Network
Support Group for Parents of Children with Liver Disease
Mr. Robert Mederios, State Amvet Commander

For further information contact Service Officer James F. Mullin at 436-2911 between 9 & 4.

Michael J. Mylett

Michael J. Mylett
Commander

The Drive will take place at the Post located at 4 Hill Top Street Dorchester.

4 HILL TOP STREET, DORCHESTER, MASS. 02124 617-436-2911

John P. McKeon Post No. 146 Amvets

PRESS RELEASE

The John P. McKeon Post No. 146 Amvets, the largest Amvets Post in the country, in conjunction with the State Amvet Commander Robert Medairos and the State Department of Amvets has initiated an Organ Donor Awareness Drive to be held on March 29th along with the annual blood drive. Present at the Drive will be E. Frank Chiampoli, National Amvet Executive Committee member and Thelma Reardon, President of the Department of Mass. Amvets Auxilary. This Drive is in response to the Proclamation of Governor Michael S. Dukakis declaring March as Organ Donor Month. This Organ Donor Awareness Drive has received the full support of the New England Organ Bank, the National Kidney Foundation of Mass., the New England Eye Bank, the New England Renal Network, the MGH Bone Bank, the Skin Bank of the Shriners Burns Institute and the Support Group of Parents of Children with Liver Problems. This cooperative effort establishes a clear example of community service that may be adopted by the National Amvets organization and other groups that can address the problem of organ donor awareness. The Amvets have traditionally been involved with blood drives. The McKeon Post feels that this Organ Donor Awareness Drive will benefit those many patients who are currently waiting for transplant surgery. The Registrar of Motor Vehicles representing the Governor will formally recognize the Post for its effort.

Jamie Fiske, liver transplant recipient, whose search for a liver donor received national attention will be present with her family at the Post on this day. The Fiske family is keenly aware and supportive of the Amvet's willingness to respond to this genuine health need.

For further information call: Service Officer James F. Mullin at
436-2911

State Department of Amvets 727-2972

The Drive will take place at the Post located at 4 Hill Top Street, Dorchester between 3:00 and 8:00 PM. The Address Ceremony will be held between 3:00 and 4:00.

4 HILL TOP STREET, DORCHESTER, MASS. 02124 617-436-2911

John P. McKeon Post No. 146 Amvets

March 29, 1983

ADDRESS CEREMONY

General Introduction Commander Michael J. Mylett

Formal Recognition to Governor Michael S. Dukakis through his representative Registrar Alan A. Mackey

Review of Official Correspondence Commander Mylett

Brief Summations

- Robert Medairos, State Amvet Commander
- E. Frank Ciampoli, National Amver Executive Committee
- Thelma Reardon, President Dept. of Mass. Amvets Auxilary
- Benjamin A. Barnes M.D., Secretary-Director New England Organ Bank
- John Curley, Executive Director, National Kidney Foundation of Massachusetts
- Phillip Walters, Skin Bank Shriners Burns Institute
- Jeff West, Support Group for Parents of Children with Liver Problems
- Valerie Belcher, Executive Director, New England Eye Bank
- Jamie Fiske, Liver Transplant Recipient

Concluding Remarks Commander Mylett

4 HILL TOP STREET, DORCHESTER, MASS 02124 617-436-2911

The Commonwealth of Massachusetts

By His Excellency

MICHAEL S. DUKAKIS

Governor

A PROCLAMATION

1983

WHEREAS: March has been proclaimed Organ Donor Month in the Commonwealth of Massachusetts; and

WHEREAS: The Registry of Motor Vehicles maintains an Organ Donor Program and is committed to its implementation ; and

WHEREAS: All citizens of the Commonwealth have been urged to take cognizance of that event and participate fully in its observance; and

WHEREAS: The John P. McKeon Post No. 146 Amvets in conjunction with State Department of Amvets has willingly responded to that Proclamation through the initiation of an Organ Donor Awareness Drive to include the New England Organ Bank, New England Eye Bank, Skin Bank of the Shriners Burns Institute, National Kidney Foundation of Massachusetts, New Engalnd Renal Network, Support Group for Parents of Children with Liver Disease; and

WHEREAS: The John P. McKeon Post No. 146 Amvets and the State Department of Amvets have fully demonstrated a commitment to educate the general public through an Organ Donor Awareness Drive; and

WHEREAS: The John P. McKeon Post No. 146 Amvets with the assistance of the State Amvet Commander and his staff have demonstrated leadership and concern for the health of the citizens of the Commonwealth and have set an example of positive response to a genuine community need; and

WHEREAS: The Amvets already have a commitment to community service and have established a precedent that may be emulated on the national level

NOW, THEREFORE, I, MICHAEL S. DUKAKIS, Governor of the Commonwealth of Massachusetts, do hereby give full recognition to the John P. McKeon Post No. 146 Amvets for its initiative and leadership in establishing an

ORGAN DONOR AWARENESS DRIVE

as a response to my Proclamation of March as Organ Donor Month.

Given at the Executive Chamber in Boston, this twenty-fourth day of March, one thousand nine hundred and eighty-three, and of the Independence of the United States of America, the two hundred and seventh.

By His Excellency the Governor

Michael S. Dukakis
MICHAEL S. DUKAKIS

Michael Joseph Connolly
MICHAEL JOSEPH CONNOLLY
Secretary of the Commonwealth

GOD SAVE THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF MASSACHUSETTS

AMVETS

AMERICAN VETERANS OF WORLD WAR II, KOREA AND VIETNAM

Chartered By Act
of Congress
July 23, 1947

ROOM 542, STATE HOUSE BOSTON, MASSACHUSETTS 02133 Telephone: 727-2972

April 5, 1983

Mr. Charles Fiske
100 Bayberry Ave.
Bridgewater, Ma. 02324

Dear Charlie:

This letter is to thank you, and Jamie on behalf of AMVETS (American Veterans of WW II, Korea, and Vietnam) for making AMVETS aware of the need to show people how important it is to donate a vital organ for someone, somewhere, lying in bed waiting to be helped.

You as a father of a loved one, have gone through this experience and torment of one closed door after another. If it was not for your persistence, and your love for Jamie, we as AMVETS would not be involved in such an important program of telling people throughout the country about "Organ Awareness", and how to donate a vital organ so that someone will live.

I, as the State Commander was proud on March 29th of the turnout of AMVETS, and people who care, and the coverage we received by the news media, and TV. Also, the fact that it was held at the largest AMVET Post in the country, the John P. McKeon Post #146.

As a State Department, we have endorsed this as a Program, in conjunction with our Blood Drive.

I am a candidate for National Vice Commander of Programs. If I am successful in this endeavor, I hope to make "Donor Awareness" a Program on a National level.

Sincerely,

Robert A. Medairos

Robert A. Medairos,
State Commander
Department of Massachuset

RAM/vs

WE *Fought* TOGETHER . NOW, LET'S *Build* TOGETHER

The Commonwealth of Massachusetts
Department of Public Welfare
600 Washington Street, Boston 02111

THOMAS H. SPIRITO
Commissioner

October 29, 1982

Mr. and Mrs. Charles E. Fiske
100 Bayberry Circle
Bridgewater, MA 02324

Dear Mr. and Mrs. Fiske:

The Department of Public Welfare is happy to inform you that based on the information submitted on behalf of Jamie, approval is given for payment of her medical treatment and for a liver transplant to be done at the University of Minnesota Hospital.

Since Jamie has Blue Cross/Blue Shield coverage, all claims must first be submitted to the private insurer. Payment to the hospital can only be made by Massachusetts Medicaid at the rate authorized by Medicaid in Minnesota, less any payment made by Blue Cross.

Physicians who customarily bill private patients for their services may be reimbursed according to the Massachusetts Medicaid Fee Schedule for physicians, less any payment made by Blue Shield.

Medicaid Provider Applications will be sent to the hospital separately. After a provider number is obtained, complete policy and billing instructions will be sent.

We wish Jamie a beneficial outcome of her treatment.

Sincerely,

Thomas H. Spirito
Commissioner

THS:JK:mv

cc: Brockton CSA
John S. Najarian, M.D.
Annette Jorbin, University of Minnesota Hospital
Joan Keefe

Blue Cross
of Massachusetts

100 Summer Street
Boston, MA 02106

October 1, 1982

Hospital Administrator
University Of Minnesota Hospital
420 Delaware St. S.E.
Minneapolis, MN 55455

Re: Jamie Fiske - Identification No. 7324233

Dear Sir:

Hospital expenses incurred, for services related to the liver transplantation for Jamie Fiske, will be paid for by Blue Cross. Although the terms of our contract exclude coverage for liver transplantations, due to the extenuating circumstances in this particular case, we have made an exception.

All hospital billings should be directed to Blue Cross and Blue Shield of Minnesota for processing.

I sincerely apologize for any inconvenience this may have caused you.

Sincerely,

Philip A. Litos
Hospital Claims Department

cc: Patient Account Manager
University of Minnesota Hospital
Mr. Charles Fiske
Ms. Annette Jorbin

Mr. **Gore**. We appreciate so deeply your willingness to share your experiences with us.

We are going to have some questions, if you can be patient with us for a moment. Our procedure is to have the panel testify and then come back for questions.

There is a common thread here. Michele Jones benefitted from the same sort of elevated awareness that led to an organ for Jamie.

Mr. Skeen, would you like to introduce Michele?

Mr. **Skeen**. Mr. Chairman, I think that you could go on and introduce her, so we can get on with the testimony, but thank you very much.

Mr. **Gore**. Michele Jones was awaiting a kidney transplant when there was a television show that highlighted the problems of organ procurement. A young person was watching that show and made the comment that he would like it to be known that he would have his organs donated if there was ever a tragedy. As fate would have it, not long afterwards there was an accident, and that is what led to Michele's operation.

Michele, could you describe your experiences for us?

Ms. **Jones**. Thank you, Mr. Chairman, members.

My name is Michele Jones. I am 22. I just graduated from Lubbock, Tex., Texas Tech University.

My parents were told when I was 4 years old that I had abnormally small kidneys. In 1972 they diagnosed this as bilateral renal hypoplasia manifesting itself predominantly from renal or tubular defects.

At this time, they told me that I should have no children. They mentioned that I would go on dialysis. I had no idea what it was. I had no idea what the transplant would include. As far as I knew, I would go straight from the way I was living then right into a transplant. I didn't know you would have to go through finding a donor through tissue typing or anything like this.

In August of 1978 additional reviews were made, and they decided that renal disease was either hereditary or congenital, with regional scarring.

My attitude on life at this time had turned very negative. At 12 years old you really don't think about having children, but it is kind of in the back of your mind. As I grew older, the more I thought about it, the more it was like a sword. It just got worse and worse, until it made my attitude towards marriage and toward life in general very, very bad, very negative. I really didn't care for it. I didn't want anything to do with it. I didn't want to take the chance of passing it on to my kids.

Basically, I had very bad mood swings. It affected my mental outlook very much. In my junior year in college, my kidney really started getting bad. My skin started turning yellow. My mental process, I couldn't think as clearly. I had to sleep all the time, it seemed like.

On July 1, 1981 I got kicked in the face by a horse, which had nothing to do with my kidneys quitting. So, I was in ICU. When the doctors came in and started cutting on my wrist to put a shunt in, I had no idea what they were doing. I didn't know what they were going to do when they hooked me up to a machine. I didn't know what it was supposed to do.

When I finally could start talking, so I could ask them questions, they told me what dialysis included, that it sent your blood through a machine to purify it, to get rid of the waste products that your kidney was supposed to get rid of and didn't.

Mentally, it was a very big adjustment, going from being able to do anything I wanted to to being restricted to twice a week going to a dialysis center, 4 hours at a time. I had to work my school schedule around it, my work schedule, life schedule. If I didn't feel good when I got off the machine, I had to cancel anything I had planned for after that.

Some of the side effects of dialysis were if they got you too dry, your legs would cramp. You might have nausea, headaches, dizziness. Sometimes when I was driving home after dialysis I would have peripheral blindness. I couldn't see to the sides.

I got this feeling when I was driving down the road that I could run over anybody and I would never feel it. It was a very strange feeling, to know that you could do something like that. It was like I couldn't be hurt. That was the sensation I got after dialysis sometimes.

My mental attitude improved greatly during my dialysis treatment time, the years I was on it. I had a better outlook. It made me grow up, I guess, in the sense I had to learn to adjust to many life situations; to plan on something that had to be changed, then I could do it more easily.

One of the problems I noticed on dialysis—not on the machine, actually—was in traveling, you had to let a center know at least two weeks in advance that you were going to go there. Sometimes you couldn't get on, they didn't have room for you, they didn't take out of state or out of town patients. Sometimes you didn't let them know far enough ahead of time, and many times the towns didn't have a dialysis center.

So, if I had continued on dialysis I think this would have affected my working because if I had gone into being a sales representative, as I was going to, this would have limited the regions I could have traveled, the places I could have gone. I would have worked completely around this scheduling of dialysis.

Also, when I was on dialysis they used a Gortex graph in my arm, and it had clotted off three times since I had had it put in. The last time was the Monday before I got the transplant.

That was another thing. Eventually I would have run out of places for them to put graphs or fistulas. They would have had to go subclavian, and then I would have had to stay in the hospital. Other than the inconvenience, I could have stayed on dialysis, probably, except for mentally it was getting to me very much.

Before the transplant, I did some living-related blood tissue typing. We had gone through this for over six months. We were having various problems with the center I was working with in Dallas, getting this all worked up. They didn't tell us what to expect on a transplant, where the kidney was going to go, or anything like this.

On January 1, I did get on the cadaver list. I tried to get on there before, but they said I could not get on the cadaver list and be working up the family-related at the same time.

In January I got on the list. On February 4, they called me up the first time and told me I had a kidney. I told them that I was sick, I had a cold, and they would not let me have it. They said, "We have other people that could benefit from this kidney. We will check with them first." They went ahead and checked and found one that was acceptable.

I would like to say, here, that kidneys like many other organs are not that easy to come by. I was lucky. I was considered an easy match. I had not had many blood transfusions. I had not built up many antibodies. Many transplant patients have had blood transfusions, and major operations which make it harder to match them.

I would also like to say that the emergency room doctor can make the difference in usuable organs. A person may come in to emergency, declared brain dead, and the doctor may not keep the person alive. Where if the doctor had kept the person on a life support system; as they did my doner, the organs that the person wants donated can be. A lot rests upon the emergency room doctor's shoulders as to whether organs are usuable or not.

The 15-year-old boy who donated his kidney was watching "Thursday's Child" on February 1, the week before he was legally declared dead, and he donated both of his kidneys, which went to Dallas, his corneas stayed in Tyler, they did use some of his skin at a burn center, and his heart went to St. Louis.

When they called me Monday morning, I was on dialysis. They said, "You have got a kidney. Get here as soon as you can." It took us three hours to get to the Lubbock airport and then fly to Dallas. Blood typing was done again. It took 4 to 6 hours for them to do that, before they could say a definite yes or no with this kidney.

I had the surgery done at 9 o'clock in the morning, Tuesday morning, on February 8. There were no complications. It took about 4 hours. The doctor said I had a 78-percent acceptance rate at that time, and it will increase as the years go on.

These are some of the side effects of some of the medicines I am taking, which are Prednisone and Imuran. Short term, with Prednisone you develop a moon face, your acne increases, like you are going through being a teenager again, you gain weight, your appetite is increased, but as the Prednisone levels are decreased, most of these effects also decrease.

Long term, they told me that I could develop skin cancer much easier, that whenever I did go out in the Sun I had to put a Sun screen on; that I would have joint problems, basically hip joint problems, that they could replace that; that I would also have the possibility of coming up with cataracts, which they could also fix.

Mentally after this I think I have been much better. My mood swings have completely gone. I have a much better attitude on life. I look forward to it now. I see challenges. Because I have overcome this much, surely nothing else could stop me.

Some of the things I have to watch after, since I have had the transplant, is my immune system is much lower. Especially the first month or so I watched who I was around, I stayed out of crowds, and I kept a very good check on my temperature and weight gain.

Something that I am going to have to watch from now on is my blood pressure, which I take twice a day, and my temperature, which I take twice a day. I check my weight every morning before I eat.

As far as eating is concerned, while I was on dialysis I was on a restricted diet. I was on a low potassium, no salt, high protein diet plus liquid restriction of 500 cubic centimeters plus output. After the transplant I was still restricted on the salt and still on high protein. No I have to eat foods with potassium to keep up with my body's needs. The liquid restriction is gone, now I have to drink as much as I can, in order to keep my kidney flushed, and to keep my output up. Basically the diet has changed a fair amount in that now I can eat many more foods than I could before, especially fruits.

I have to stay on my Imuran and Prednisone, as far as I know, for life, every morning, I can't skip at all. If I do skip, the possibility of rejection goes up very quickly. Dr. Pedro Vergne, who is my nephrologist, said if my temperature got above 100, first to call him, and they would check to see if it wasn't a rejection before they doctor me for anything else.

I don't anticipate having any problems. I haven't really had any. I have been in and out of the hospital three times since the operation, but none of them were kidney-related that they could figure out.

As far as plans for later on, I plan on getting a sales representative job with Marion Laboratories and continuing as I should, now that I am what I consider normal.

Mr. **Gore**. Thank you very much, Michele. We will have some questions for you in just a moment.

We would like to hear from the president of the National Kidney Foundation and from the executive director of the American Liver Foundation.

Dr. David Ogden, in addition to being president of the National Kidney Foundation, is professor of medicine and chief of the renal section at the University of Arizona Health Science Center.

Dr. Ogden, without objection your entire prepared statement will be put into the record in full. We invite you to proceed. If you care to summarize any of your statement, feel free to do so.

Dr. **Ogden**. Thank you, Mr. Chairman, and members of the committee.

I appreciate the opportunity to speak to this committee on behalf of the thousands of lay and multidisciplinary professional volunteers of the National Kidney Foundation, which is the leading voluntary health organization dedicated to the needs of people with kidney and urologic diseases.

I would comment in four areas. I should indicate that my comments pertain particularly, if not entirely, to kidney disease, which is the area in which we have particular interest and expertise.

First, the role of the National Kidney Foundation in organ procurement; second, the present status compared to the potential of organ procurement; third, the results of a recent Gallup organization survey concerning the attitudes and opinions of the American public toward kidney donation; and finally, measures to enhance organ donation in the United States, as suggested by both our Gallup survey and by the Foundation membership.

The National Kidney Foundation organ donor program began 15 years ago with the support of the Uniform Anatomical Gift Act. Since then, the foundation has printed and distributed over 30 million donor cards, including 900,000 cards which were distributed through a cooperative effort with the Lutheran Church.

The Foundation and its more than 50 affiliates actively supported the individual State driver's license organ donor checkoff laws, which now provide for people to donate organs in all 50 States, or to indicate their willingness to donate organs. The value of this option in enhancing public awareness of organ donation has been tremendous, as evidenced perhaps from the Gallup survey.

The Foundation conducts an active and ongoing program in support of kidney transplantation and organ donor publicity, both through its own publications and through broader media. Recent efforts include arrangements by our affiliates of numerous radio and TV appearances and over 100 newspaper articles which describe Arnold Beher's "Gift of Life," 9,000 mile, zigzag, cross-country bicycle tour with a bicycle powered by a transplanted kidney.

It includes Foundation support of the U.S. team's participation in the 1982 Fourth International Transplant Olympics held in Athens, Greece, and includes the just completed organ donor blitz, in which a number of members of Congress signed organ donor cards and in which the President of the United States met with National Kidney Foundation officials and endorsed the concept of organ donation.

The present status of organ procurement can be judged from the number of kidney transplants performed compared to the number of kidneys that are potentially available and suitable for transplantation.

In 1981 there were nearly 2 million deaths in the United States from all causes. About 60 percent of these deaths occurred in a location that was potentially accessible to organ procurement. We estimate that of those, only 1.5 percent would meet existing criteria as potential organ donors for kidney transplantation.

I would like at this time to make the point that the criteria for potential donation of other organs are quite different, so the figures don't really pertain to hearts, livers, or other organs.

Therefore, about 18,000 dead people might have contributed two kidneys each, providing 36,000 potential kidneys. Of those, for various technical reasons, no more than about 75 percent, or perhaps 27,000, might be considered actually transplantable. An additional 10 percent wastage might be experienced in locating a suitable recipient.

So, there might have been 24,000 kidneys available for actual transplantation. In fact, 3,425 cadaver kidneys were transplanted in 1981. That is about 14 percent of the potential organs available. It is estimated that at any point in time, there are 6,000 to 8,000 U.S. dialysis patients waiting for cadaver kidney transplants.

The Gallup organization survey, commissioned by the National Kidney Foundation, was conducted from January 14 to January 22 of this year. Of a nationally representative survey sample of almost 1,600 people age 18 and over, 93 percent had heard of organ transplants and 76 percent had heard of organ donor cards. Eighty-five percent of respondents were aware that organs were only sometimes or rarely available when needed.

Thus, the American public is remarkably aware of the issue and of the problem. Perhaps more remarkably, 83 percent of those aware of organ transplants indicated that they were very or somewhat likely to donate the kidneys of a loved one, although only 40 percent were very or somewhat likely to want their own kidneys donated after death.

The reasons most often cited for not wanting to donate their own kidneys were, "I never really thought about it," 20 percent of them, and "I don't like the idea of cutting me up after I die," another 20 percent.

Of those who are very or somewhat likely to donate their own kidneys after death, 31 percent had signed a donor card. If the sample is truly representative of the U.S. adult population, then approximately 21 or 22 million adults have actually signed donor cards.

It is apparent that the shortcoming in organ availability is not a lack of public awareness or public education. It is not a lack of public willingness to grant permission for organ donors after death. Indirectly, then, the survey indicates that the greatest potential for enhancing cadaver organ availability is in identifying potential cadaver donors and appropriately requesting consideration of organ donation of family members.

Mr. Chairman, I am attaching a copy of an executive summary of this survey to my testimony. I would like it to be published as part of my testimony.

Mr. GORE. Without objection, we will include that in the record.

Dr. OGDEN. The key elements of a successful organ procurement and transplantation system include, first, surveillance by hospital personnel; second, potential donor identification by hospital and/or medical personnel; notification of the transplant coordinator; preliminary donor evaluation; pronouncement of death by the patient's own physicians; informed consent of the next of kin obtained by the transplant team; the donor surgery; donor tests, including tissue typing; identification of potential recipients; transport of the donor organ to the recipient; final recipient tests; and finally recipient transplantation.

The Gallup survey suggested enhanced organ donation can most likely be achieved by attention to surveillance by hospital personnel, identification of potential donors, notification of the transplant coordinator, and appropriate request for informed consent from the next of kin.

The remaining elements of the system I have described are largely in place and function more or less well in every large community in the Nation.

Therefore, the National Kidney Foundation specifically recommends that the Joint Commission on Accreditation of Hospitals be asked to require that every JCAH approved hospital of 150 beds or more document the existing donor status from each patient's driver's license at the time of admission, recording this status on the admission form; that in the event of admission or transfer to any intensive care unit from the emergency room or any floor of those hospitals, the existing donor status be determined from the admission form and recorded on the ICU transfer form or intake form and in the initial intensive care unit nursing note.

Compliance with these measures would be determined at the time of JCAH review and would be a factor in JCAH approval of the hospital's operation.

We suggest that the American Medical Association and State medical societies be asked to encourage all physicians, through the chairman of the medical staff, to include in any "no code" or any "brain death" progress note a notation of potential suitability for organ donation and acknowledgement of existing donor status as it is recorded on the admission record; and that all physicians be encouraged to notify the area transplant coordinator when in his or her professional judgment a dying patient may be a suitable transplant donor, whether or not the patient had previously indicated an intent to be an organ donor.

We recommend that all appropriate medical and voluntary health agencies and the Department of Health and Human Services encourage all State legislatures to enact a uniform brain death law in those States that currently are without such legislation.

Finally, that continuing medical education be encouraged by physicians and by professional and voluntary health organizations concerning the identification of potential donors, concerning organ donor procedures, and concerning the results of transplantation, and that these continuing medical education efforts be targeted particularly to intensive care unit nursing and physician personnel, emergency room nursing and physician personnel and neurologists and neurosurgeons.

I would like to thank the members of this committee for your attention and for this opportunity to testify.

Mr. GORE. Thank you.

[The prepared statement of Dr. Ogden follows:]

April 14, 1983

Testimony of David A. Ogden, M.D., F.A.C.P.,
President, National Kidney Foundation

Mr. Chairman, Members of the Committee:

My name is David A. Ogden, President of National Kidney Foundation, and Professor of Medicine at the University of Arizona College of Medicine. I appreciate the opportunity to speak to this committee on behalf of the many thousands of lay and multi-disciplinary professional volunteer members of the Foundation, which is the leading voluntary health organization dedicated to the needs of people with kidney and urologic diseases.

My comments will concern four subjects:

1. The role of National Kidney Foundation in organ procurement;
2. The present status, compared to the potential, of organ procurement;
3. The results of a recent Gallup Organization Survey of the "Attitudes and Opinions of the American Public Towards Kidney Donations";
4. Measures to enhance organ donation in the United States as suggested from the Gallup Survey and by the Foundation membership.

National Kidney Foundation Role:

The National Kidney Foundation Organ Donor Program began in 1968, with support of the Uniform Anatomical Gift Act. Since then, the Foundation has printed and distributed over 30,000,000 donor cards, including 900,000 cards distributed by means of a cooperative effort with the Lutheran Church, in the September, 1982, issue of The Lutheran Witness, the official periodical of the Lutheran Church - Missouri Synod. The Foundation and its more than 50 Affiliates actively supported the individual State's driver's license organ donor check-off laws, which now provide for people in all 50 States to indicate their willingness to be an organ donor. The value of this option in enhancing public awareness of organ donation has been tremendous, as evidenced from the Gallup Survey.

The Foundation conducts an active and ongoing program in support of kidney transplantation and organ donor publicity, through its own publications and through broader media. Recent efforts include arrangements by our Affiliates of numerous TV and radio appearances, and over 100 newspaper articles describing Arnold Beher's "Gift of Life" 9000 mile, zig-zag, cross country bicycle tour with a bicycle "powered by a transplanted kidney"; Foundation support of the U. S. Team's participation in the 1982 IVth International Transplant Olympics held in Athens, Greece; creation, with the generous support of the American Contract Bridge League, of a dramatic film about kidney transplants titled "Bridging the Gap"; sponsorship of a one and a half day Science Writers Seminar in Washington concerned significantly with recent advances in organ transplantation, and resulting in many newspaper articles nationwide; and the just completed Organ Donor Blitz during which a number of members of Congress signed organ donor cards and the President met with NKF officials and endorsed the concept of organ donation.

The Foundation also met with representatives of HCFA, the ESRD Networks, and representatives of the Emergency Medical Services (EMS) Program to help establish a program to inform EMS staff of potential donor characteristics, and to foster a working relationship between EMS Coordinators and Regional Organ Retrieval teams.

Present Status of Organ Procurement:

The present status of organ procurement, based on 1981 figures (the last year for which accurate data is available), can be judged from the number of cadaver kidney transplants performed, compared to the number of kidneys potentially available and suitable for transplantation. In that year, there were 1,987,000 deaths in the U.S. from all causes, 60% of which, or 1,192,000, occurred in locations potentially accessible for organ procurement. Only 1.5% of these people would meet existing criteria as potential organ donors for kidney transplantation. Thus, 17,830 dead people might have contributed two kidneys each, providing 35,760 kidneys (criteria for donation of hearts and livers are dissimilar to criteria for suitability for kidney donation, so it cannot be assumed that similar numbers might have donated a heart or liver). Of the 35,760 kidneys potentially available, for various technical reasons, no more than 75% or 26,820 might be considered actually transplantable. An additional 10% wastage might be experienced in locating a suitable recipient. Thus 24,140 kidneys might have been potentially available for actual transplantation. In fact, 3,425 cadaver kidneys, or 14% of this number, were actually transplanted in 1981.

It is estimated that at any point in time, 6,000 to 8,000 U.S. dialysis patients are waiting for a cadaver kidney transplant. This number might change with the improving science of and results of cadaver transplantation, and might increase simply if cadaver organ availability increased, shortening the waiting time for some patients and increasing the probability of suitable tissue matching for hard-to-match patients.

The Gallup Organization Survey:

The National Kidney Foundation commissioned the Gallup Organization, Inc. to conduct a survey of "Attitudes and Opinions of the American Public Towards Kidney Donations" from January14-22, 1983. Of a nationally representative survey sample of almost 1,600 persons age 18 and over, 93% had heard of organ transplants, and 76% had heard of organ donor cards. Eighty-five (85%) percent of respondents were aware that kidneys were only sometimes or rarely available when needed. Thus, the American public is remarkably aware of the issue and the problem. We would like to think that this is reflective, in part, of the efforts of the National Kidney Foundation to educate the public in this area.

Perhaps more remarkably, 83% of those aware of organ transplants indicated they were very or somewhat likely to donate the kidneys of a loved one, although only 40% were very or somewhat likely to want their own kidneys donated after death. Reasons most often cited for not wanting to donate their own kidneys after death were "I never really thought about it" (20%), and "I don't like the idea of someone cutting me up after

I die" (20%). Of those very and somewhat likely to donate their own kidneys after death (40%), 31%, or 12.4% of the entire sample, had signed a donor card, and 41%, or 16% of the sample, had told their family members of their wishes. If the sample is truly representative of the U.S. adult population, then approximately 21-22 million adults have signed donor cards and 29 million adults have told their family members of their wishes to donate.

A great deal more detailed information is contained in the Survey, an Executive Summary of which is available from the National Kidney Foundation, 2 Park Avenue, New York, NY 10016. However, from the information above, it is apparent that the shortcoming in organ availability is not a lack of public awareness or education, and it is not a lack of public willingness to grant permission for donation of organs after death. Indirectly, the Survey indicates that the greatest potential for enhancing cadaver organ availability is in identifying potential cadaver donors, and appropriately requesting consideration of organ donation of family members.

Measures to Enhance Organ Donation:

Typically, factors cited as inhibiting organ donation have included 1) lack of public awareness; 2) lack of public and professional education; 3) failure to philosophically recognize death as a natural part of life; 4) the fact that 28 States do not have a "brain death" law; and 5) the lack of a nationally coordinated organ donor network, including the logistic complexity of a national matching program.

The Gallup Survey suggests that although there is room for further public education, factors 1, 2, and 3 above are not major factors inhibiting organ donation. Certainly most medical professionals are at least as aware of organ donation as is the general public. Education of medical professionals concerning potential suitability of and recognition of suitable donors for various needed organs must be on-going. Passage of a brain death law by States not now having such a law would surely be of some benefit in increasing organ donation, but cadaver organs are currently obtained in States without brain death laws, and the absence of such a law has not been shown to greatly inhibit organ donation. Regional Organ Procurement Programs now exist in and cover virtually all regions of the country. Increasing telephone and computer links of these regional programs has produced a fledgling National Network. In any event, few organs are now wasted because of failure to identify a recipient. I am confident that, if the availability of organs increases, the organ sharing system will adapt and expand such that these organs will not be wasted.

The key elements of a successful organ procurement and transplantation system include:

A. Surveillance by Hospital Personnel

B. Potential Donor Identification by Hospital and/or Medical Personnel

C. Notification of Transplant Coordinator

D. Donor Evaluation - Preliminary

E. Pronouncement of Death by Patient's Physicians

F. Informed Consent of Next-of-Kin Obtained by Transplant Team

G. Donor Surgery

H. Donor Tests - Tissue Typing

I. Identification of Recipient(s)

J. Transport of Donor Organs

K. Recipient Tests - Final

L. Recipient Transplantation

The Gallup Survey indicates that family members, if identified and asked, are likely to grant permission for organ donation. This suggests that enhanced organ donation can most likely be achieved by attention to surveillance by hospital personnel, identification of potential donors, notification of the Transplant Coordinator, and appropriate request for informed consent from the next-of-kin. The remaining elements of the system are largely in place and functioning well in every large community in the nation.

Therefore, the National Kidney Foundation specifically recommends:

1. That the JCAH be asked to require that:
   A. Every JCAH approved hospital of 150 beds or more document existing donor status from each patient's driver's license at the time of admission, recording this status on the admission form; and
   B. In the event of admission or transfer to any intensive care unit (ICU) from the emergency room or any floor of the above hospitals, existing donor status be ascertained from the admission form and recorded on the ICU transfer form (intake form) and in the initial ICU nursing note.

Compliance with these measures would be determined at the time of JCAH review and would be a factor in JCAH approval of the Hospital's operation.

2. That the AMA and State Medical Societies be asked to:
   A. Encourage all physicians, through the Chairman of the Hospital's Medical Staff, to include in any "No Code" or "Brain Death" progress note, a notation of potential suitability for organ donation and acknowledgement of existing donor status as recorded on the admission record; and
   B. All physicians be encouraged, as in number 3 above, to notify the area Transplant Coordinator, when, in his or her professional judgement, a dying patient may be a suitable potential transplant donor, whether or not the patient had previously indicated an intent to be an organ donor.
3. All appropriate medical and voluntary health agencies, and the Department of Health and Human Services encourage all State legislatures to enact the Uniform Brain Death Law in those States currently without such legislation.
4. Continuing medical education be encouraged by physicians, professional and voluntary health organizations concerning identification of potential donors, organ donor procedures, and results of transplantation, and be targeted particularly to ICU nursing and physician personnel, ER nursing and physician personnel, neurologists and neurosurgeons.

I would like to thank the members of this committee for the opportunity to provide this testimony.

ATTITUDES AND OPINIONS OF THE AMERICAN PUBLIC TOWARDS KIDNEY DONATION

EXECUTIVE SUMMARY

Prepared For:
THE NATIONAL KIDNEY FOUNDATION

Prepared By:
THE GALLUP ORGANIZATION, INC.
53 Bank Street
Princeton, New Jersey, 08540

GO 8305

February, 1983

BACKGROUND AND METHODOLOGY

The National Kidney Foundation, as part of its plans for a national education campaign on the need for kidney donations for those needing kidney transplants, commissioned The Gallup Organization, Inc. to conduct a survey of the American public on attitudes towards kidney donations.

The survey was conducted by in-person interviews among a nationally representative sample of 1,574 persons age 18 and over. Interviewing was conducted during January 14 through January 22, 1983.

THOSE WHO ARE MORE LIKELY TO WANT THEIR OWN KIDNEYS DONATED AFTER DEATH ARE MORE EDUCATED; WITH HIGHER INCOME; WHITES RATHER THAN BLACKS

Those who are most likely to want their own kidneys donated after their death are those who have completed more formal education and are in higher income brackets (two interactive variables). Blacks are much less likely than whites to want their own kidneys donated (10% vs. 27%). These same demographic characteristics distinguish those more likely to give permission for the kidneys of a loved one or their own child to be donated.

MANY RESPONDENTS SAY THEY HAVE NEVER REALLY THOUGHT ABOUT IT WHEN ASKED TO RATE VARIOUS REASONS AS BEING "VERY IMPORTANT"

About one in five (20%) say that a very important reason for not wanting to have their kidneys donated after their death is that "I never really thought about it".

DISLIKE FOR IDEA OF BEING CUT UP AFTER DEATH CITED AS "VERY IMPORTANT" BY ONE IN FIVE

About the same proportion (20%) cite as "very important", the reason "I don't like the idea of somebody cutting me up after I die". No other reason was cited by that large a proportion of respondents as being "very important".

FEW SAY THAT RELIGIOUS REASONS OR COMPLICATED PERMISSION PROCEDURES ARE VERY IMPORTANT

Only 7% say either that the reasons "it is against my religion" or that "it is complicated to give permission" are very important reasons for not wanting their own kidneys donated after their death.

DISLIKE FOR THE IDEA OF BEING CUT UP AFTER DEATH IS THE REASON WHICH MOST SHARPLY DIFFERENTIATES THOSE MORE AND LESS LIKELY TO WANT OWN KIDNEYS DONATED

The greatest difference between those more and less likely to want their own kidneys donated is in their response to the reason: "I don't like the idea of somebody cutting me up after I die". Only 5% of those who say they are very/somewhat likely to want their own kidneys donated characterized that reason as being "very important", compared with 44% of those who are not very/not at all likely, more than twice the difference of each of the eight other reasons presented.

FEW HAVE TAKEN ACTIONS TO IMPLEMENT THEIR INTEREST IN HAVING THEIR OWN KIDNEYS DONATED AFTER THEIR DEATH

Less than half (41%) who say they are very/somewhat likely to want their own kidneys donated after their death have told family members about their desires. Even fewer (31%) have signed an organ donor card; told close friends (18%); told a doctor (5%); or put it in their will (4%).

AWARENESS OF ORGAN DONOR CARDS IS VERY HIGH

Seventy-six percent of those interviewed say they have heard of organ donor cards. Even among those not likely to want their own kidneys donated, 76% had heard of the cards; almost two-thirds of blacks interviewed (65%) had heard of them.

A SMALL PROPORTION OF THOSE AWARE OF ORGAN DONOR CARDS HAVE SIGNED THEM

Only 18% of those aware of organ donor cards have signed one. Even among those likely to want their own kidneys donated, only 35% have signed a card.

MOST CORRECTLY ASSESS CONSEQUENCES OF SIGNING ORGAN DONOR CARDS

Virtually all aware of organ donor cards and virtually all who say they have signed an organ donor card believe correctly that the following two statements are false:

> "If you signed a card, someone can force you to give up one of your kidneys when they need one for a transplant."
>
> "Once you have signed a card, you cannot change your mind."

VERY HIGH LEVEL OF BELIEF THAT A CENTRAL FILE OF CARD SIGNERS EXIST

Almost two-thirds of those aware of cards, and half of those who have signed cards believe, erroneously, that the following statement is true:

> "There is a central file of people who have signed donor cards which is made available to doctors or others who are trying to locate a kidney donor."

ABOUT ONE-THIRD BELIEVE THERE ARE KIDNEY BANKS, AS THERE ARE BLOOD BANKS

About one-third (31%) of those aware of organ transplants believe, erroneously, that there are kidney banks, just as there are blood banks. This is equally true of those more or less likely to want to have their own kidneys donated. Those who have signed an organ donor card are less likely (23%) to believe this is true.

VIRTUALLY NO ONE BELIEVES THAT DONATED KIDNEYS ARE "ALWAYS" AVAILABLE, "OFTEN" AVAILABLE, OR "NEVER" AVAILABLE

Those respondents with an opinion split about equally between believing that donated kidneys are "sometimes" available (44%) or "rarely" available (41%).

THOSE WHO ARE LEAST LIKELY TO WANT THEIR OWN KIDNEYS DONATED AFTER THEIR DEATH ARE MOST LIKELY TO BELIEVE THAT KIDNEYS ARE "RARELY" AVAILABLE WHEN NEEDED

Those who have signed organ donor cards are more likely to say that kidneys are "sometimes" available, rather than "rarely" available (47% to 39%). This is true, as well, among those who are very/somewhat likely to want their own kidneys donated (49% say "sometimes" available; 38% say "rarely" available).

However, among those who say they are not very/not at all likely to want their own kidneys donated, only 36% say that they think donated kidneys are "sometimes" available, with 46% saying they are "rarely" available.

VIRTUALLY NO ONE BELIEVES THAT KIDNEY TRANSPLANTS EITHER HAVE LITTLE OR NO EFFECT ON THE RECIPIENT'S LIFE, OR THAT THEY MIGHT SHORTEN THAT PERSON'S LIFE

Even among those who say they are not very/not at all likely to want their own kidneys donated after their death, no more than 1 or 2 percent chose either of these two responses as characterizing the effects of kidney donation on the person receiving a kidney transplant.

MORE BELIEVE THAT A KIDNEY TRANSPLANT CAN "EXTEND THAT PERSON'S LIFE SUBSTANTIALLY" THAN THAT IT "MIGHT OR MIGHT NOT EXTEND THAT PERSON'S LIFE"

When presented with four possible effects of a kidney transplant on a recipient, about half of all those surveyed who are aware of transplants chose the response: "can extend that person's life substantially", and another 42% chose the response "might or might not extend that person's life".

As expected, more of those who signed an organ donor card (61%), and more of those who are very/somewhat likely to want their own kidneys donated (60%) chose the response: "can extend that person's life substantially".

Those who are not very/not at all likely to want their own kidneys donated are significantly less likely than others to choose the response "can extend that person's life substantially" (40%), and significantly more likely than others to choose the response "might or might not extend that person's life" (46%).

Mr. **Gore**. Our last witness on this panel is the executive director of the American Liver Foundation, Mrs. Thelma King Thiel.

Mrs. Thiel, we are delighted to have us with us this morning.

Mrs. **Thiel**. Thank you, Mr. Chairman, members of the committee.

I am the executive director of the American Liver Foundation, and I would like to mention that the American Liver Foundation has only been fully operational for about 3½ years. Typically, the noncomplaining liver has been sadly neglected over the years.

I am also the founder of the Dean Thiel Foundation, one of the first foundations in the country to focus on liver diseases, the fourth leading cause of death in our Nation. My son, Dean, in whose memory the foundation was named, would have been 17 years old today.

He was diagnosed at 2 weeks of age of having cirrhosis of the liver from biliary atresia. Each day of his 4 years on Earth I prayed for research to find an answer to save his life. I hoped and prayed, but my hope was transparent. Little was known and even less was shared with us as desperate parents.

Today there is true substance to the word hope. The replacement of diseased organs is possible. Today we can roll away the stone of death and give new life to babies, children, mothers, and fathers with liver transplants.

As the mother of a child who suffered the agonies of hell for 4½ years, I felt angry, cheated and crushed beyond belief to lose my precious son. Seventeen years ago a life-saving liver transplant was not within our grasp. Today the story is different, thank goodness. There is hope, miraculous hope. But with that hope comes the frustrations and new problems.

Liver transplants can save lives if a donor of the required age frame can be found and the liver retrieved quickly. Another if relates to the money. A new liver, a renewed life is attainable, if enough money is available to pay for this costly procedure.

The American Liver Foundation receives calls daily from desperate individuals pleading for help. Where can they get the money to save their child's life? The only answer that we can give them is to contact your legislators, contact your insurance company, and go to the media. We are actually telling them to go out with a tin cup and try to pay for their child's liver transplant. I know how they feel. Our time ran out, but their clock is still ticking.

In the 13 years since my son died, I have dedicated my life to finding the answers to liver diseases. I am proud to be working with the American Liver Foundation toward this end. We welcome this opportunity to share our concerns with you and to help find solutions for some of these agonizing problems.

Over the years the lower level of funding for liver research has resulted in a severe lack of diagnostic tools to identify many of these insidious diseases until irreparable damage has been done.

Effective treatments and cures are almost nonexistent for many of the 100 liver diseases that attack children, as well as adults. Most Americans know very little about their livers and how to prevent liver diseases.

Liver transplantation, a last resort procedure just a few years ago, is the only hope for survival for thousands of Americans suffering with incurable liver diseases. The cost of a liver transplant represents an investment in the restoration of a productive life for victims of liver disease.

The need for more liver transplant centers and trained transplant surgeons is evident. The need for donors, a current problem, will increase dramatically in the next few months as several more transplant units are established.

How can we possibly meet the demand for more donors? How can we stop the incredible waste of life-giving organs, lost daily through ignorance, indifference and perhaps fear? If physicians and other health care providers could only feel, for just one moment, the deep sense of anguish of a parent whose child's life is slipping away, they would not permit this tragic waste to occur.

Unfortunately, they cannot walk in our shoes. Therefore, we must constantly remind them of the critical need for donors. They are on the front line. They are touching and feeling the pain of their patient and his family. They can help to ease that pain by suggesting that another life can go on through an irreplaceable gift that they alone can give.

What greater gift can any of us give than one of life itself? This giving of life may be, at the time, the only light in a sea of dark despair. One that can go on glowing for years to come, giving comfort and solace to those who have suffered an irreplaceable loss.

We must leave no stone unturned to seek out and retrieve all possible organs. The ALF would like to recommend the following actions:

First. Heighten awareness of the public about the need for organ donation through all possible media. Government and lay organizations can work together in this effort. A clearinghouse could also help in this major role.

Second. Provide donor cards on the reverse side of all drivers' licenses. Some states still need legislation to provide this service. We could encourage this through our driver education programs.

Third. Inform physicians and nurses and allied health professionals about the critical need for organs. Of course, the American Hospital Association, the American Medical Association, some of the lay and professional organizations could get involved in this area.

Fourth. Establish criteria for recognizing brain death as death through each state department of health.

Fifth. Establish a protocol for determining brain death in each hospital through the Joint Commission of Accreditation of Hospitals. This would be an appropriate medium for calling attention to the need for donors and for emphasizing the positive benefits and comfort families can derive from donating life-giving organs to victims of incurable diseases.

Sixth. Publicize in every health facility in the nation the hotline numbers for donor procurement and donor information. Every emergency room, intensive care unit and operating room should have prominent posters identifying these numbers, to save time. Time is critical, especially for the retrieval of livers. There is an extreme urgency to expedite the process. The Department of Health and Human Services could probably help in this effort.

Seventh. Finally, costs must be controlled. We must continue to support the research to improve diagnosis, treatments and the management of transplant patients while still supporting basic research to find cures. In particular, we must work to find reasonable answers to the cost of liver transplantation and support efforts to fund this therapeutic procedure.

Thank you for calling us all together to help develop a plan for saving lives. The American Liver Foundation will continue to work to reduce the tremendous human suffering caused by liver diseases.

[The prepared statement of Thelma King Thiel follows:]

AMERICAN LIVER FOUNDATION

TESTIMONY

OF

THELMA KING THIEL

Vice Chairman and Executive Director

American Liver Foundation

Before

The Subcommittee on Investigations and Oversight

Committee on Science and Technology

Chairman, Albert Gore, Jr.

April 14, 1983

AMERICAN LIVER FOUNDATION

I am Thelma King Thiel, Executive Director and Vice Chairman of the American Liver Foundation, Vice Chairman of the National Digestive Diseases Advisory Board and an Advisor to the National Digestive Diseases Education and Information Clearinghouse.

I am also the Founder of the Dean Thiel Foundation (DTF), the first health agency to focus attention on liver diseases, the 4th leading cause of death between ages 15-65. DTF is an affiliate of the American Liver Foundation.

My son Dean, in whose memory the Foundation was named, would have been 17 years old today. He was diagnosed at two weeks of age as having cirrhosis from a liver disease called biliary atresia. Each day of his four years on earth, I prayed for research to find an answer to save his life. Research to me, at that time, was an illusion . . . an undefined entity that might be able to create a miracle. I HOPED AND PRAYED . . . but my hope was very transparent. Little was known and even less was shared with us as desperate parents.

Today there is true substance to the word HOPE. The replacement of diseases, almost petrified organs, is possible. Today we can roll away the stone of death and give new life to babies . . . children . . . mothers and fathers with liver transplants.

As the mother of a child who suffered the agonies of Hell for four years, I felt ANGRY . . . CHEATED . . . CRUSHED beyond belief to lose my precious little boy. 17 years ago, a life saving liver transplant was not within our grasp . . . Today the story is different. There is HOPE . . . MIRACULOUS HOPE.

But, with that hope come new frustrations . . . new problems.

Liver transplants can save lives IF . . . . . .

IF a donor in the required age frame can be found and the liver retrieved quickly.

Another IF relates to money.

A new liver . . . a renewed life is attainable, IF enough money is available to pay for this costly procedure. The American Liver Foundation receives calls daily from desperate individuals pleading for help. Where can they get the money to save their child's life?

Frankly, ladies and gentlemen, I would have sold my soul if I had had a chance to save my son's life. I know how they feel. Our time ran out . . . but their clock is still ticking.

In the 13 years since Dean died, I have dedicated my life to finding the answers to liver diseases and am proud to be working with the American Liver Foundation toward this end. We welcome this opportunity to share our concerns with you and to help find solutions for some of these agonizing problems.

Over the years the low level of funding for liver research has resulted in a severe lack of diagnostic tools to identify these insidious diseases until irreparable damage has occurred. Effective treatments and cures are almost non existent for many of the 100 liver diseases that attack children as well as adults. Most Americans know little about the liver and the prevention of liver diseases. Liver transplantation, a last resort procedure just a few years ago, is the only hope for survival for thousands of Americans suffering with incurable liver diseases. The cost of a liver transplant represents an investment in the restoration of a productive life for victims of liver disease. The need for more liver transplant centers and trained transplant surgeons is evident. The need for donors, a current problem, will increase dramatically in the next few months as several more transplant units are established.

How can we possibly meet the demand for more donors?

How can we stop the incredible waste of "life giving" organs, lost daily through ignorance, indifference and perhaps fear?

If physicians and other health care providers could only feel, for just one moment, the deep sense of anguish of a parent whose child's life is slipping away . . . they would not permit this tragic waste to occur.

Unfortunately, they can not walk in our shoes. Therefore, we must constantly remind them of the critical need for donors. They are on the front line. They are touching and feeling the pain of their patient and his family. They can help to ease that pain by suggesting that another's life can go on through an irreplaceable gift that they alone can give. What greater gift can any of us give than one of life itself. This giving of life may be, at the time, the only light in a sea of dark despair . . . but one that can go on glowing for years to come . . . giving comfort and solace to those who have suffered an irreplaceable loss.

We must leave no stone unturned to seek out and retrieve all possible organs every day. The list of recommended actions should be implemented as soon as possible.

1. Heighten awareness of the public about the need for organ donation through all possible media. Government and lay organizations can work together in this effort.
2. Provide donor cards on the reverse side of all drivers licenses. Some states still need legislation to provide this service.
3. Inform physicians, nurses and allied health professionals about the critical need for organs.
4. Establish criteria for recognizing brain death as death through each state department of health.
5. Establish a protocol for determination of brain death in each hospital through a Joint Commission of Accreditation of Hospitals. This would be an appropriate medium for calling attention to the need for donors . . . and for emphasizing the positive benefits and comfort families can derive from donating life giving organs to victims of incurable diseases.
6. Publicize in every health facility in the nation the Hotline numbers for donor procurement and donor information. Every emergency room, intensive care unit, and operating room should have prominent posters identifying these numbers, to save time. Time is critical, especially for retrieval of livers. There is extreme urgency to expedite the process.
7. And finally . . . costs must be controlled. We must continue to support research to improve diagnosis, treatments and management of transplant

patients while still supporting basic research to find cures. In particular, we must work to find reasonable answers to the cost of liver transplantation.

Thank you for calling us all together to help develop a plan for saving lives.

AMERICAN LIVER FOUNDATION

YOUR LIVER - your most complex organ . . . yet the least understood

Liver Diseases are the fourth leading cause of death in Americans between the ages of 15 and 65. Until 1976, however, no national organization existed to focus attention on the human suffering and economic burden resulting from liver diseases. The American Liver Foundation is acting as a catalyst to develop a national sense of urgency that will increase the research needed to have a significant impact on this sadly neglected health problem. Liver diseases are on the increase and represent a major health hazard.

Liver diseases cause:
- 50,000 deaths annually
- $10 billion estimated economic cost
- 1 million hospital admissions annually

In addition:
- 32,000 deaths a year due to cirrhosis
- 8,000 deaths from cancer of the liver annually
- 20 million Americans have gallstones
- 500,000 gall bladder operations performed yearly
- 500,000 to one million new cases of hepatitis each year

Tragically, little has been done to address the increasing problem of liver diseases. Why?

One problem is the lack of information about liver diseases among the general public. They are unaware that liver diseases have many causes including:

- severe reaction to drugs (prescribed as well as over the counter)
- several types of viruses
- excessive use of alcohol
- prolonged exposure to environmental chemicals
- inherited and inborn abnormalities
- parasitic conditions

Patients often suffer from the stigma attached to liver diseases - a stigma based on the misconception that liver diseases affect only alcohol and drug abusers. Rather than endure this misunderstanding, patients conceal their illness, masking the magnitude of the problem.

The low level of funding for research directed to liver and biliary tract diseases has caused progress to be slow in fighting liver diseases.

More researchers and increased funding are needed to investigate liver problems. Many opportunities for advancing knowledge in liver function and disease are lost because the initial funds are insufficient and the potential for continued support is uncertain.

More liver specialists teaching in medical schools are needed to improve the quality of care provided by newly trained physicians.

ALF, 998 Pompton Avenue, Cedar Grove, NJ 07009

AMERICAN LIVER FOUNDATION

American Liver Foundation Research Programs

An increased investment in liver research is essential to discovering cures and treatments that will lessen the human suffering and economic burden that liver diseases inflict on us all. The American Liver Foundation gives researchers the opportunity to select and remain in liver research by funding the following programs:

- Student Research Fellowship awards for medical and doctoral students to stimulate their interest in liver research at a time when they are making career choices.
- Postdoctoral Research Fellowship awards of $7500 which supplement N.I.H. fellowship grants to provide a living wage for young researchers.

Education of Health Professionals

The Foundation sponsors continuing medical education courses for physicians and other health professionals on the important advances that have occurred in the diagnosis, pathology and treatment of liver diseases - an important means of improving patient care.

Public Education

The American Liver Foundation is reaching large numbers of people to increase awareness that liver diseases are a serious, neglected health problem. Informing the public is accomplished through television, radio, newspapers and magazines. ALF also distributes accurate, easy to understand literature on viral hepatitis, cirrhosis, liver diseases in children, cancer of the liver, primary biliary cirrhosis and others.

Pediatric Liver Council

The American Liver Foundation has developed the Pediatric Liver Council to address particular needs in the area of children's liver diseases for research, education, training of health professionals and family support. By publishing a newsletter, SHARING CARES AND HOPES, the Pediatric Liver Council provides a means for families to share their concerns and give support to one another.

Coordination of a National Effort Through Chapters

For those afflicted with liver disease, a sense of hope is essential: To meet this need, the American Liver Foundation is organizing and coordinating mutual help groups through its Chapters to provide emotional support for patients and their families, make referrals to specialists when appropriate, and keep people abreast of the latest research developments through special programs such as "Meet the Researchers." These Chapters are assisting in educating the local community and increasing awareness of the need for more research as well as providing grass root support for all national programs.

How is the American Liver Foundation Funded?

As a non-profit, tax-exempt, national health agency, the American Liver Foundation receives funds directly from the general public and through its Chapters in the form of memberships, memorials, bequests and from special fund raising events. In addition, the American Liver Foundation is the recipient of grants from corporate and private foundations.

ALF, 998 Pompton Avenue, Cedar Grove, NJ 07009

SHARING cares and hopes SHARING cares and hopes

AMERICAN LIVER FOUNDATION
PEDIATRIC LIVER COUNCIL
998 Pompton Avenue, Cedar Grove, N.J. 07009

Winter 1983

Sharing concerns with others who are experiencing similar problems builds a special bond of friendship and understanding. It helps to provide the strength and courage to face the uncertainty of the days ahead. Many heavy burdens of care have been lightened by sharing joys and heartaches with those who understand.

We are pleased to publish another issue of Sharing Cares and Hopes and invite you to call or write us to add your name to our list of thoughtful and concerned friends.

"A GRANDPA'S LOVE"

My little Anneliese
How I have loved you from the start
Sharing with me your quaint little ways
You have stolen your Grandpa's heart
I have watched you touch both young and old
Cloaked in courage for all to behold
With innocence of child you have questioned not
As you have walked through the valley of doubt
Unselfish in love, undaunted in faith
A child's teaching of what life's all about
O' my precious little Annie
You symbolize what our Lord means life to be
When he spoke "Suffer the little children to
come unto me"
May I always be humble, even in moments of grief
and dispair
To know I was among those chosen in your
precious little life to share
And should the Lord send forth His angels
That we must bow to His command
I shall keep the child's faith you taught me
To know such things are wisely planned.

* * *

Our 7 year old daughter Anneliese has Biliary Atresia. She is jaundiced, has an extended stomach, terrible itching and Cirrhosis which has caused her to have 2 episodes of internal bleeding. We are pleased to share this poem that was written for our daughter by her grandpa.

Eugene and Jerri Kedziorski
4248 A Street, S.E., #425
Auburn, WA 98002
206-939-9697

November 27, 1978 will always be a special day in my life. On that day I lost my four year old daughter, Beth, to a disease known as Biliary Atresia. It hurt and it probably always will. A part of my heart belongs to her and even though I have two other children, 7 and 2 years of age, no one will ever take her place. We were waiting for a liver transplant for Beth when she died. I was furious because they weren't able to find a liver for my daughter. I finally came to terms with these feelings and decided that I had had Beth for four and a half wonderful years. I gave my daughter everything I had to give and more. She touched all our lives in a very special way. She enriched my life and showed me, that no matter how badly losing her hurt, life goes on. If there's anyone else who's been through the same pain as I have, please write or call. It would help to know I'm not alone.

Nancy Coppolino
7 Elm Street
So. Barre, MA 01074
617-355-2742

Rachel Joy had a Kasai operation for her Biliary Atresia when she was 3 months old. She's a very happy little girl now at 13 months of age. She has a problem with fluid retention and Cirrhosis, although her bilirubin count has been steadily dropping. She is on a low sodium diet and Portagen - loves puffed wheat! We know that she's the Lord's, but are praying that someday she will be able to receive a successful liver transplant. We also have a 6 year old daughter, Julia, who is very loving and understanding. We are very thankful for our Chapter and Christian friends and family who are so helpful to us.

John and Carol Van Walbeek
2326 Springbrook Drive, N.E.
Cedar Rapids, IA 52401
1-319-393-5562

My son Scott is eight years old and in the second grade. He was diagnosed with Alpha 1 Antitrypsin when he was a baby. I believe in the quality of life and strive to help Scott to lead as normal a life as possible. Talking to other parents in similar situations has been helpful. Only through sharing thoughts, experiences and feelings can we grow and learn to make life for us and our children the best it can be. I would love to share with other parents of children with liver diseases.

Linda Bramble
3207 Highland Boulevard
Highland, MI 48031
313-887-2954

Pamela was born 5 1/2 years ago with Biliary Atresia. After 3 Kasai Procedures and several additional hospitalizations, Pamela now functions as a normal kindergartener. She plays the piano, goes to dancing school and even attends summer camp. She is our miracle and our joy and we cherish each day that we share with her. We know that Pam has Cirrhosis and a bilirubin which continues to climb. We live with the hope that either a medical breakthrough or transplant will allow her to live a long and normal life. In 1981, I initiated efforts with my N.J. Congressman, Senator and ALF to meet with Surgeon General Koop and others to express our concerns about the role which the Federal government might assume in liver transplant research, support for the financially burdened families of patients and the reclassification of transplantation from "experimental" to "therapeutic." Subsequent meetings were held and this June a large Consensus Conference open to the public, will take place in Washington to explore the entire issue of liver transplantation. I have found that working toward a goal both with the Foundation and my local and Federal officials has helped channel my energy and initiative in a positive direction. Much more needs to be done and I welcome the opportunity to talk to others with a similar perspective.

Gail and Jeff Rempell
41 E. Cheryl Road
Pine Brook, NJ 07058
201-575-3654

Little Emily Heiple jogs around the dining room table, loves dressing up in her mother's clothes, and attends Kindergarten. She has a contagious smile which she loves to flash when she's in trouble for writing on the walls. She has one natural sister and an adopted brother and sister. She's the least disciplined of the 4 which can be explained by her spending most of her first 2 years of life in Rochester, Minnesota undergoing 4 operations for Biliary Atresia. Emily is fast approaching her 6th birthday in spite of elevated liver function tests. She remains non-jaundiced but has Cirrhosis and portal hypertension. Her energy level far surpasses the rest of the family. She usually wears everyone down while leaving a trail of messy rooms behind as evidence. It is difficult to think about the future and what that means for Emily and our family. We are interested in sharing with other families how we have learned to live one day at a time and enjoy it.

Rita and Joe Heiple
111 Graceline Boulevard
Waterloo, IA 50701
319-235-6986

Our Sara, age 3, appears to be as normal and active a child as any in La Porte, Indiana. Certainly her three surgeries and 11 hospitalizations are not apparent in her snappy brown eyes and bouncy walk. Sara has Biliary Atresia, but has responded to surgical revision to drain bile. Sara is one of a group of children treated at Riley Hospital in Indianapolis, who are non-jaundiced and growing well after successful Kasai Procedures. A biopsy late last summer indicated Sara's liver is functioning well and incurring no new Cirrhosis. Sara frequently talks about her painful experiences. Even her dolls all nave I.V. shots, medicines, etc. We are so grateful that the real tragedy of chronic liver disease has not been her fate. The wasting away, swollen belly, lack of lustre and energy are not part of Sara's exuberant life.

Randy and Nancy McGriff
108 Lawrence Street
La Porte, IN 46350
219-362-7395

Our daughter, Michele, was diagnosed as having Chronic Active Hepatitis at age 8. She developed a secondary immune-complex disease after beginning medication. She experienced a number of side-effects from Prednisone the first year of her illness. Michele is now 12 and currently takes Prednisone and Imuran. She has not developed Cirrhosis and has almost full liver function. She is active in sports and only has occasional problems from her illness. We would be happy to communicate with other Chronic Active Hepatitis patients.

Stan and Janice Lange
2024 North Street
San Angelo, TX 76901
915-949-0244

Our son, Alex, now six years old, was born with a genetic enzyme deficiency of the liver, Alpha 1 Antitrypsin Deficiency. This deficiency was diagnosed at birth, because of prolonged jaundice and other problems. So far, our prayers have been answered, and he is our miracle boy, since his liver appears to be functioning adequately. However, we continue to pray that an effective long-term treatment can be found. Our newest addition, another little boy, was born perfectly healthy. We beat the odds!

Mrs. G. Bertram Wells
3112 Old Crow Court
Lexington, KY 40502
606-266-0379

Our daughter, Susie, was born June 16, 1978. She seemed to be a happy and healthy baby but became jaundiced at one month. After two biopsy's she was diagnosed as having Byler's Disease, a hereditary disease of the liver. She is now 4 1/2, is jaundiced and itches constantly. She is behind most children her age and has a hearing problem due to frequent ear infections. Our only hope for this very special child God has given us would be a liver transplant one day. We would like to write to others to share our special concerns.

Owen and Clara Miller
R #3 16020 Nash Road
Middlefield, OH 44062

Our beautiful 26 month old daughter Summer was diagnosed at 2 months as having Biliary Atresia. Her Kasai was done at that time with a biliostomy. She had a fair amount of drainage and it was reconnected when she was 21 months old. Her condition is stable but her Cirrhosis is considerably advanced. When she was 2 she was examined in Pittsburgh for a transplant but nothing will be done unless she gets worse. This uncertainty is murderous! We are starting a Chapter of ALF in Houston. We would love to talk to anyone concerning liver disease.

Debbie and Tommy Martin
1506 Sue Barnett
Houston, TX 77018
713-686-1770

Lauren was diagnosed at 13 months with hereditary Tyrosinemia. The prognosis was grim. We spent a long time trying to deal with that tragic sentence. Our lives and values changed dramatically. Our family, friends, and even some doctors had never heard of Tyrosinemia. We wanted to talk with other families with Tyrosinemia but none of our medical contacts were able to help. A year later, through a friend, I heard of the American Liver Foundation. I called Thelma Thiel, Executive Director of the Foundation, who knew of another family with a similar problem and we were able to talk to them. At 2 1/2 cancer was diagnosed in Lauren's liver, and she was given 3 to 6 months to live. The idea for a liver transplant came from "Sharing Cares and Hopes." I called Thelma for her input, and she gave me Dr. Thomas Starzl's phone number. Five days later we were in Pittsburgh for transplant evaluation. After much public appeal and the enormous generosity of many people, Lauren had transplant surgery in November '81. She looks great, has enormous energy, and loves nursery school. The American Liver Foundation played a vital role in saving Lauren's life.

Beatrice and Joseph Toohey
12 McKinley Drive
Kinnelon, NJ 07405
201-492-0920

Our daughter, Alesha, died Christmas Day 1982. In April, at 2 months, she had been diagnosed as having Biliary Atresia. The Kasai Procedure was done although no major bile ducts were found. Two days after she left the hospital bile began to flow. Alesha was stable until October when a serious infection set in. A call to the American Liver Foundation brought us information and much needed support from Veronica Otterberg of ALF's Omaha, Nebraska Chapter. Her condition worsened in November and we realized that a transplant was only life saving option and found that the cost was very high and at this time she was too small to have the surgery. We decided to set up a trust account and began to raise funds to defray the cost of a liver transplant. Having spent a week in the hospital before Christmas, Alesha's condition had stabilized enough for us to take her home Christmas eve. She was alert and we had a wonderful loving time with the whole family. That night our little darling died peacefully in my arms. We are grateful for the thoughtfulness and concern we received from our dear friend Veronica and the ALF. We thank them for their work in education, research and providing mutual support for parents and families. We would be willing to share the concerns of others.

Glenda and Vince Mahaney
Route 4
Denison, IA 51442
712-263-6686

Micki is planning to go to College in the fall. At 17, her Chronic Active Hepatitis with Cirrhosis is in remission and she is involved in many extra curricular activities at school and has a part time job. Micki recently did a term paper on liver transplants and is extremely interested in new advances in research. We have made some marvelous friends and are coping much better with Micki's Hepatitis. We'd like to help others the way we've been helped through sharing our concerns with others.

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Mr. **Gore**. Thank you, Mrs. Thiel.

We will now have questions for the panel.

We have two beneficiaries of transplants on this panel. There are so many others who are awaiting transplants. The subcommittee has been literally flooded with letters from parents from around the country. Some of them have been provided by you, Mr. Fiske, and we have been flooded with pictures of beautiful children who are waiting for transplants. Clearly we need a national strategy to solve this problem.

In addition to research and development, it seems to me there are three issues, in ascending order of importance. The first is a better organization for organ procurement; second, the removal of the funding obstacles that so many families have to hurdle; third, and most important of all, the raising of the awareness in this country of how important organ donation is.

We could solve most of this problem if families across this country had a conversation over the dinner table or at the breakfast table and said to each other, as a family we think that organ donation is a good idea, that we hope no tragedy ever occurs in our family, but if one dies, at least it could lead to hope and joy for some person who might not live without an organ transplant.

Mr. Fiske, I want to ask you a question about that issue first.

What would you say to a family that was having a conversation around their dinner table and somebody in the family spoke up and said, "Well, I just don't think that organ donation is a good idea. I am a little nervous about it. I don't like to think about it. I don't like to think about dying. I don't like to think about an organ being removed after death." What would you tell that person?

Mr. **Fiske**. I think, Mr. Chairman, you have probably hit the nail on the head by saying that it is families themselves, talking like that informally, where the change really does take place.

I think my first response to anybody like that, the fact that it is even talked about is encouraging. The fact that somebody says no, I don't think it is a good idea, they are raising the issue within the family. I think that is probably very encouraging. If that takes places, then it is a very optimistic sign.

I think what I would suggest to any family where that does come up is to keep talking about it. To cram that idea down somebody's throat, to force them into it is not the way to go.

I think probably the clearest example of that in our case was the Bellon family, having two children, at 5:30 at night, happening to have the TV on and making that decision subconsciously at that point. The following Tuesday they had done it. I think it has to be a free kind of choice and it has to be an ultimate gift kind of choice.

I would suggest to family members, if there is that kind of resistance, what are the obstacles to that. What is the reason for not doing that, and respecting that kind of decision because I think that really has to remain there, that each individual does have that choice to say I don't think it is a good idea.

I think it is healthy to keep bringing that up. I guess that is what I would recommend, is to continue talking about it.

It is easier to talk about it around particular cases. You are talking about two very difficult situations. On the one hand, the donor person who is going to be declared brain dead, and the other person who will die by not having a transplant. They are both very difficult concepts to handle.

It becomes a bit more understandable around individual cases. Michele is probably a good example right here because she has had the benefit of that kind of giving. Jamie is a good example.

The whole issue of transplantation across the board is a hard one to understand. If you take a look at Jamie, with Jamie right now, there are two other children that I have seen. I don't think I have ever met them, but I would say that both of those children have some form of end-stage liver disease that probably will need a transplant at some point.

I think when people see these two children side by side, to say Jamie was where these children are, that is a good thing to do. Even though it may be difficult to talk about dying, it may be difficult about talking about those issues, Jamie directly benefited from the Bellon family in Utah taking the time to give that gift of life.

If it is made very concrete, and if that is done over a period of time and people discuss it, then it doesn't become so conceptual. It becomes something that a family can say take a look at Jamie, here she is, as the pictures demonstrate the before and the after. There is a marked difference.

I guess that is what I would suggest.

Mr. **Gore**. I think that is a very effective way to do it. I hesitate to ask this of any of the families who have come here, but do you care to say something? If you care to speak to the subcommittee—I know this is unusual and I will ask my colleagues' indulgence—Dr. Ogden, if you could let her take your seat briefly, we could take Mr. Fiske's advice and just paint the issue in as stark terms as possible.

Your name, ma'am, is?

Mrs. **Goode**. Virginia Goode. I am from Morningside, Md. This is Nicky.

Mr. **Gore**. You live in the area?

Mrs. **Goode**. Yes.

Mr. **Gore**. And your child's name?

Mrs. **Goode**. Nicholas Goode. He is 22 months old. He has biliary atresia. He has been waiting for 5½ months for a donor.

Mr. **Gore**. He has the same condition that Jamie Fiske, right behind him, had?

Mrs. **Goode**. As does the little girl over here, who is 13 months old. She is Candy Thomas.

Mr. **Gore**. How old is your child?

Mrs. **Thomas**. One year old.

Mr. **Gore**. And the name of the child?

Mrs. **Thomas**. Candice.

Mr. **Gore**. Candice Thomas is the child's name.

In other words, the point you were trying to get across, Mr. Fiske, is much more clearly illustrated by the difference between these two children.

Mr. **Fiske**. I think it is a gift of life situation, where you are talking about the opportunity of giving life to somebody else through some kind of generous thinking about it. With our situation, the

Bellon family, in the midst of the death of their son, Jess, thought about life for Jamie.

So you have two contrasting kinds of ideas: the one issue of dying, but also in the process of that, extending and giving life to somebody who desperately needs that particular organ. Jamie is a good example of receiving a gift of life in the midst of a death situation with the Bellon family.

Mr. GORE. Mrs. Goode, you are still waiting for an organ to be donated for your child, is that correct?

Mrs. GOODE. Yes, sir.

Mr. GORE. Mrs. Thomas, you are still waiting for an organ to be donated for your child, too?

Mrs. THOMAS. Yes.

Mr. GORE. Biliary atresia, also?

Mrs. THOMAS. Yes.

Mr. GORE. And you are from the local area, also?

Mrs. THOMAS. Accokeek, Md.

Mr. GORE. Thank you very much. I appreciate that very much. Mr. Fiske, I have one other question and then I want to turn to my colleagues.

On the question of funding, I think it is very important to note that if someone in your situation, in your home town, went back to the same Blue Cross-Blue Shield company and asked for funding of a liver transplant, they would be likely to be turned down. Isn't that correct?

Mr. FISKE. To answer very clearly what they said to me in writing, "Due to the extenuating circumstances in this particular case, we have made an exception."

Mr. GORE. In other words, because of what they regarded as a mistake and then because of the enormous amount of national publicity, they made an exception in your case. But there are other cases where families need a liver to be transplanted to save the life of their child, where the same company will refuse to pay for it.

Mr. FISKE. The other thing I think that should be mentioned is that liver transplants are not the way to go to treat liver disease. If I can put that in context, Jamie had an extremely difficult situation with biliary atresia. Other procedures were tried ahead of time. She had an 8-hour operation in February, and a 4-hour operation in July. The last treatment of choice was a liver transplant. If we didn't have to go through that, we would not have. We had no other choices at that particular point in time.

What was happening, too, is the sicker that Jamie got the higher the medical costs got. If you take a look at her hospital bills from July 6 through the date of transplant, they increase markedly because she was declining at a rapid rate. After that, they reached a peak with the transplant and then declined.

On December 16 she left, and the only hospital bill that we have had facing us from Blue Cross-Blue Shield is that 2- to 3-day checkup in Minnesota, which was to see how she was doing. It is somewhat cost effective to have given her the liver transplant.

Mr. GORE. It is a good point. We certainly hope that we can change the financing policies of the Federal Government and the private insurance companies to save lives and, as you point out, to save money, too. It is ironic that it would do both at the same time.

Congressman Skeen?

Mr. **Skeen**. Thank you, Mr. Chairman.

I would like to comment on how traumatic I am sure it is for those of us who have never been touched by this kind of a problem to say well, this evening we are going to read the Bible and right after that we are going to have a discussion about being an organ donor.

That probably ought to be a good procedure in a family, if they only knew how important this discussion might be. I think it was pointed out in the testimony that the media has played an extremely important part.

We are fond, in the great halls of this body, of castigating the media time after time for some of the things that they don't do, but very seldom do we ever give them credit for some of the good things that they do. I know that it creates some problems, too, insofar as ethics about whether the media influences, gives someone an advantage and so on. However, they have done an outstanding job in this area, as has been pointed out in both cases today, I know in Michele's.

It is very difficult for people to overcome a natural repugnance at the idea of talking about donating organs. It is something that we need as a society to learn to do, is to get over the idea that there is something wrong or bad about talking about leaving parts of ourselves.

There is only one way besides procreation on this earth that you can extend life, and now we have the technology to do that. It is another form. I think you said it very well, Mr. Fiske, that this is a new way to give life. The technology involved in the medical world, the pharmaceutical world, and so forth is a great gift and one we should take advantage of.

I want to ask Michele a question because I know that in our own family circle—Michele, you did an outstanding job. You weren't nervous at all during your testimony; I told you it would be OK.

I know that Michele had a question in her mind. This young lady has had to take the brunt of making those decisions, where the family could help only to a certain degree. Mr. Fiske had a different type of a problem. Mr. and Mrs. Fiske had to make the decisions for their child. But one of the difficult decisions that Michele had to make was whether or not to go family donor or to go ahead and consent to a cadaver donor.

Michele, I would like to know, how did you finally change your mind? I know for some time you had decided that you would only accept an organ from some member of the family. I know it was a tough decision for you, but it changed the whole outlook on your problem. How did you finally make that decision? Was it tough?

Ms. **Jones**. Well, when I started I was going to go living-related. I had five family members to choose from. Through the tissue typing they had decided my sister was the best choice. She was a perfect four match. But she said no because she had two small children that she was worried about, who may develop kidney problems sometime that she might want to donate to.

The other four members were a two match. My one brother had said he would like me to go cadaver first. He was a law student, and he was starting his last year of school and wanted to get into practice.

It had gotten down to the three other members, my mom, my father, and my other brother. They sat there and bounced it back and forth between the three of them on who had lived the best so far, like I have lived the longest, I have lived a full, happy life. If something should happen to me on the table, then we have nothing to complain about. My brother would say no, I should, we need to have the parents around.

They went back and forth with this so much and they would not let me decide. It was something that I couldn't decide for them. Finally, I think I got so fed up with them not making a decision, not deciding, that I decided cadaver, that was the way I was going to go.

I also released the pressure from them. I was releasing pressure from other family members outside of the immediate family, like my aunts, because they had worried about my father donating because there had been kidney problems on both sides of the family on my dad's side. My mom had had kidney stones, which wasn't really related to what I had. Finally I said that's it, I am going cadaver. I did get the transplant.

Mr. SKEEN. I think it is an important element in this discussion because here again is a situation created where everyone wants to help, but within a family it can cause such an aura of tension, so you have to learn to deal with this kind of a problem as well.

I think it is far easier to discuss among the family the possibility before an acute problem occurs. I think every family ought to do this and should they be asked, be ready to make the decision that at your death you want to donate organs. Otherwise the alternatives that this young lady had were extremely difficult and almost caused an alienation within the family.

That is just another one of the things that is happening. I think it is extremely important.

I would like her to elaborate on the financing. Michele, how are you financing your operation?

Ms. JONES. When I first started on dialysis, we tried to go through Blue Cross-Blue Shield. It took much, much help from you and from several others to get Blue Cross-Blue Shield going and start making payments. As soon as we got medicare stepping in and taking over 80 percent, Blue Cross-Blue Shield has kind of backed out of the picture. That is one thing I would like to say about it.

Mr. GORE. Will my colleague yield?

Mr. SKEEN. Certainly.

Mr. GORE. One of the problems that the liver patients face is they don't have the kind of funding mechanism that Congress established for kidney transplants. Medicare will now pay for kidney transplants, but liver patients have to mount either a nationwide publicity campaign or in some other way raise the funds on their own before they can even get on the list.

Mr. Fiske said that Jamie couldn't even get on the list to be considered for a transplant until he could work out the financial considerations with Blue Cross-Blue Shield. It really shouldn't be that way.

Mr. **Fiske**. She was placed on the list on the 29th of September, the same day that Blue Cross-Blue Shield authorized funding for that.

Mr. **Gore**. So just as soon as you got the authorization, she was put on the list?

Mr. **Fiske**. She had gone out there for a 2-week evaluation. They were ready to make that decision on that Thursday. That Wednesday, Blue Cross-Blue Shield called and said we are not going to honor the letters we have given you. She was placed on it on the 29th, the same day that they authorized payment.

Mr. **Skeen**. Mr. Chairman, I think that is an interesting point and one that we should resolve through these hearings; that is, the fact that medicaid and medicare, are willing to pay $250,000—they have that much exposure—on a person that is going to die.

On the other hand, it is more cost effective to enter into the programs of transplants at this stage, and with the stage of success that we have it would be far less expensive.

I hope that we can maybe make some kind of determination along that line as we go into the discussion on this because it would be a very interesting economic discussion. It is probably much more costly to let someone die. You lose, particularly in the case of these young patients, the productivity of a lifetime from the individual as opposed to being willing to pay for the death or absorb the cost of dying, which is extremely high in itself.

I would like to see if we can make some of these comparisons and then come up with some resolve from this group to encourage the private insurance suppliers or the private carriers, as they are called, and the Federal Government to change its mind in some regard to accept and to accommodate itself to the new techniques and new technology involved in transplants. We have made the breach now with kidneys. Why not livers and some of the rest of the transplant procedures that have proven high success rates?

Thank you very much, Mr. Chairman.

Mr. **Gore**. Thank you.

Congressman Reid.

Mr. **Reid**. Thank you, Mr. Chairman.

I would like to acknowledge the great education that I have received the last couple of days and commend you and the staff for putting this hearing together. I think the whole Congress is fortunate to have you involved in setting some of the things that we are doing.

The reason we are having this hearing is basically because Chairman Gore, as the chairman of this subcommittee, looked into different areas that needed attention in the science and technology field. I again, Mr. Chairman, publicly commend you for this hearing and certainly congratulate the staff on putting together a well-rounded panel.

I have been touched a number of times today by the statements that have been made by various people. I don't know of anything that we could do that is more important than dealing with saving lives, and that is what, in effect, we are doing today.

Mr. Fiske, let me ask you a question. This probably in the overall scheme of things is not important, but it is a question of curiosity in my own mind.

With adoptions, we do everything we can to keep the identity of the natural parents away from the child. You have had such a close relationship with this Utah family, the Bellon family, do you feel that it is desirable that you know who the donor is?

Mr. **Fiske**. I think in our circumstance we could probably only deal with the family in Utah. The general feeling we had picked up from the staff at the university hospital in Minnesota was that the donor remain anonymous.

We respected that kind of decision because it is a very, very tragic time for that family, to face that kind of issue. We knew that we would have liked to have had contact with them, but we respected the wishes of the experienced people at Minnesota suggesting that that remain anonymous.

When we got a call from the social worker at Primary Children's Hospital in Salt Lake City, she said that the family would appreciate hearing from us either by telephone or by writing.

We were delighted to be able to do that because we knew, as difficult as it was for us to talk with them, we needed to be able to say to them thank you, not even having the words to say thank you, but just to have that kind of contact to let them know that they did something for Jamie that nobody else in the country was able to do at that time; that is, to think beyond their own tragedy and to think of giving Jamie hope, the hope of getting better.

We are fortunate in our situation that the family is encouraged by Jamie doing well. The tragedy of their own situation, they are handling that now. It is, I am sure, very difficult and very painful for them to do, where their son was 11½ months old.

We couldn't say that that should be the case across the board, that everybody have contact with the donor family. We do know that in our own situation we have had contact with them.

We realize how difficult in some ways it was for them, but the thing that keeps coming through from the family when we talk with them is how is Jamie doing, how much does she weigh, is she sitting up, is she talking, thank you for the pictures that you sent out. There is that sense of extension out of their situation. We don't get from them a sense of bitterness. We do get from them a sense of hope that Jamie will continue to do well.

Right after the operation—there are high points and low points with Jamie's getting better. We could share those moments with that family because they wanted her, as well as we wanted Jamie, to get better.

How that would work for other situations and other families we really don't know, but our experience with the Bellon family in Utah, we are excited that they are excited about her doing well.

As I mentioned before, they have become part of Jamie's extended family. They, in the midst of a very tragic situation, offered hope. I think a family doing that, in the midst of a tragic situation, gives hope and gives life to that family out there that does need that particular organ. That is what we are talking about, is a gift of hope and a gift of life.

Mr. **Reid**. Mr. Chairman, I have a question I would like to ask Dr. Ogden.

Doctor, first of all, is there a need for donor centers, a central place, a regional central location where the donated organs would go? It would seem to me that many of the small institutions where people die in the sense like we heard yesterday, where their brains are gone but their bodies, they want them to keep working. Maybe we need a central location for donors of organs.

Second, the second question, would more money mean more transplants, generally, not just kidneys but things in general?

Dr. OGDEN. Let me respond to the first question first.

We don't need a donor organ center because you are speaking essentially of an organ bank. The organs we are talking about can't be banked. They have to be maintained in a living state or a recoverable-to-life state.

The time between removal of the organ from a donor and placement of the organ in the recipient varies according to which organ we are talking about. The longest is for kidneys. We don't like to see it go much beyond 24 hours, up to perhaps 36 hours.

Actually, the organ is obtained by a group, which can be local, or a group can go to the hospital to obtain a kidney or other organ. This is done all the time. Then the organ is transported to where the waiting recipient is.

The second question was whether more money would mean more organs. I think in the broad sense you can say yes, but the hangup is not specifically money. I think it is very hard to get to the real core of this.

I recognize, first of all, that almost all usable organs come from healthy, relatively young—middle-aged or less, usually—people who were doing their thing moments before or hours before and who have a sudden tragedy. In this country at this time, that usually means motor vehicle accidents, cars, motorcycles. Not always, but usually.

I am particularly gratified to see that the two transplants represented here at this table, in both instances the family of the donor came forward. I think we need to recognize that it is very difficult to have the health care team caring for the potential donor recognize the potential of that situation and come forth and suggest donation.

In fact, the health care team caring for the donor, their job is to represent the donor's interest. By the time they recognize that death is imminent, donation may be impossible. The potential donor may be in such medical condition by the time the care team caring for that patient—the physician, ICU nurses, et cetera—are willing to say this person is in fact going to die, that in fact they are not a donor anymore, they are not suitable as a donor anymore.

So, the problem of identifying somebody who is going to go around and say this is a potential donor puts that person, whoever that is—a transplant coordinator, an ICU nurse, another physician—in conflict with the best interests of the care team caring for the person who might have been or might be a potential donor.

All I am saying is that it makes it very difficult to find that fine point in time between which a person is in fact dead, or about to be brain dead, and still is not so dead that the organs are not useless.

That is part of the problem, resolving that problem. When the family suggests the potential of donation and recognizes the futility of the situation, then it becomes so much easier because they have, in fact, recognized it. It is possible now to think that way. It is possible for the care team to think that way.

Mr. **Reid**. Thank you, doctor.

Thank you, Mr. Chairman.

Mr. **Gore**. Congresswoman Schneider?

Mrs. **Schneider**. Thank you.

Mr. Fiske, I think that it is interesting to note that you went through a great deal of struggle in order to get your message across, that you were looking for a liver for Jamie. It was through the media that you were able to locate a donor.

Michele, it was pretty much the same situation. It was through the media, somebody hearing on the news that you were seeking the need of an organ transplant.

Mr. Fiske, I would just like you to make some comment as to the role you see in the future to try to improve the connection between the supply and the demand of organs, what role you see the media playing in the future.

Mr. **Fiske**. In some of the stuff that we went through, it was myself and Marilyn sitting down on a daily basis, making the kind of decisions like where to go and how to go about it. One of the things we didn't have was a clear game plan of what to do. It was the kind of day-by-day decision, once Jamie got put on the list, to figure out where to go.

Anything we did, we always bounced off the medical community in Minnesota, running it by them. One of the things we didn't want was that the media make medical decisions. We didn't want the media to come in and say—we wanted the doctors to make that kind of decision. We also wanted the doctors to know that we were taking steps. So both of us actively traded off the privacy we had with the possibility of Jamie getting better.

Our intention in going to the American Academy of Pediatrics was to go back to the medical community, to doctors, predominantly pediatricians, so that they they could raise—one of the things that I mentioned when I addressed them was that the trauma we are talking about for your situation may not have already happened.

What we were hoping was those pediatricians would go back, raise that issue in that relationship that they have with their families and the patients that they treat. It is kind of a sacred relationship that they have, where you entrust your children to the pediatrician's care. So, we went through that.

The media's involvement in that was very clear, in getting that message from New York City to Alpine, Utah. There was a family watching that, but it was in front of a medical forum that that was done.

As a result of our original intentions with that particular medical group, I have had calls from doctors. A doctor in Missouri called me. He had been at the convention. I got a call several weeks ago, and he said he had heard about that stuff. He was treating a patient named Kelly Johnson, and he wanted to know if I could give him the names of the doctors in Minnesota so he could call them. It was interesting because the thing we wanted for Jamie, this doctor had picked up on, was responding to, and getting involved in this particular case of biliary atresia.

What the role of the media is, in our situation the media were always fair to us. There wasn't a massive invasion of privacy. We turned to the media willingly and knew that what we considered as privacy, to hold on to that may cost us any help for Jamie.

Mrs. **Schneider**. I understand that, but it seems to me that your experience clearly denotes that anyone who is in a similar situation of looking for an organ ought to have a media game plan. I think that certainly that was one element that helped.

Yesterday in our testimony we heard how there are many nurses that are aware of possible deaths among some patients, and they are becoming more involved now in providing that information link, which seems to be the missing link in all of these discussions.

Mr. **Fiske**. To say the media has to be the salvation of everybody that needs a transplant I don't think is accurate. In our particular situation that was a choice that we made. That doesn't have to be the choice for every single family. It may not be.

Mrs. **Schneider**. But you succeeded, and I think it is an example where others probably will try to follow in your footsteps.

Mr. **Fiske**. What may have been right for Jamie may not be the way to go for every family. I think what has to be in place is something a lot more secure than media coverage of the situation; in other words, there has to be a system in place to do that so that the likes of myself and Marilyn don't have to go to the likes of Senator Kennedy, Senator Tsongas, Congressman Moakley, the Speaker of the House, asking them to assist us, and then going back to the media or going to the American Academy of Pediatrics.

I think what happens is that that may happen once or twice, but after a while that may lose some effect that it may have. I think what needs to be in place is something is a lot more long lasting than the immediate need of one child, something that families who are not facing this will have a sense of hope that we really didn't have.

Mrs. **Schneider**. I think it is quite clear that your comments now are indicative of how disorganized the structure is in order to solve the problem. I think that one of the efforts to solve the problem is the donor alert program, the 800 number.

Your neighbor to the south, in Rhode Island, my constituent, was here testifying yesterday. Are you familiar with the program that he has set up?

Mr. **Fiske**. I have talked with Ray Coleman. As a matter of fact, we were talking about getting together prior to this week, but our schedules were so conflicting.

I think Ray's background had been law enforcement and was very keenly aware that the role that police officers have in terms of identifying situations that are in the middle of the night, they are looking for the name of the person that may be involved in an auto accident, and their ability to say to the EMT or to the doctor, gee, this particular person here has a donor identification tag on his license, to think about that as they are bringing the person in.

I think again that is that whole other area of support personnel with the medical community. You have people like Ray who are very much involved in it from his perspective because of that group of people, called law enforcement, who see tragedy more regularly than most of us. His effort to bring that out I think again is one person who sees a need and is trying to do something for that.

It is encouraging, especially with the Pinheiro family, Ray called me the day before we came down here to mention that Justine had received notification from Pittsburgh. I think Ray is thoroughly committed to that, much as we are now as a family, because nobody should be in the same situation that we were.

If there is anything that we can do—and I am sure Ray feels the same way from his perspective—to alleviate some of that burden, as far as organ donor awareness, we are thoroughly in support of that.

Mrs. **Schneider.** I am delighted that you mention it because that is the perfect lead-in to my next comment.

As you know, this committee is going to be making recommendations after our 3 days of hearings. Granted, some of them will be very substantial in reference to the cost concerns of financing these operations. We will be discussing with the Federal officials and the medicare system what solutions are possible.

But there is obviously a need for continued citizen participation, and it seems to me that if we move along the lines that have already been initiated, for example, having the communications link with all of the doctors and nurses across the country, that is extremely vital.

I would also be inclined to make the recommendation, as Mrs. Thiel has mentioned earlier that the many groups across the country get together and work as a team to provide a support system. It is quite clear that not only is the money necessary along with the donor location, but the family also needs some kind of support system. I think that is the kind of public service that can be provided by many of these nonprofit organizations and individuals, such as yourself.

So, I am hopeful that your organizations and the individuals who are concerned will closely read our recommendations because I, for one, having come from the public sector and being a citizen activist, am supportive of all efforts such as your own, but obviously there is a need for coordination and coalition building.

I am hopeful that you will pick up that ball and keep running with it because that is a very vital part of the whole solution to this.

Mr. **Fiske.** Tuesday morning I met with the National Kidney Foundation of Massachusetts, the Massachusetts General Hospital Bone Bank and the New England Organ Bank. Their feeling was that they don't have money in their budgets to do public awareness.

Their thrust in their organizations is transplantation, identification of donor organs, preservation of those organs, but they don't have the ability to go out and educate the general public.

Their feeling very clearly, at least in the New England area, is any kind of support that they could back into, they would be willing to go hand in hand with that; if they could turn that public awareness over to a particular group to be able to do that, because again they don't have the ability to do that.

Mrs. **Schneider.** We should begin to focus on the New England region, I for one will volunteer, and I am sure I can work with Congressman Moakley and put together a couple of ideas and see if we can coordinate our efforts.

Mr. **Fiske**. Again, anything that you would need from myself and Marilyn, we would thoroughly support that.

Mrs. **Schneider**. Thank you very much. I appreciate your testimony and your presence here today.

Thank you, Mr. Chairman.

Mr. **Gore**. Congressman Durbin?

Mr. **Durbin**. Mr. Fiske, Mrs. Fiske, when you were waiting for that letter from Blue Cross, did you have a contingency plan in mind, what you were going to do if they said no?

Mr. **Fiske**. The overriding thought in our mind—and this is, again, speaking for both of us—was we did not want Jamie to die. I think what happened was Jamie had a very healthy period from 2 months to about 5 months and then the disease she had advanced pretty quickly. Anything we could have done we would have done.

Again, funding very clearly is an obstacle and it caused us a lot of aggravation, a lot of worry, and it could have meant her not getting that operation.

I wish that was the only obstacle. The biggest obstacle that we faced that we had no control over was her declining health. The second major one was identification of a donor. After that, I would put the issue of funding.

That is not to downplay the role of funding, but making her better and identifiying $100,000, if it was that simple, then you would do that. If we thought getting $100,000 would make her better and we would go back to Massachusetts and say goodbye Minnesota, it would have been great.

Funding did present an obstacle. I think what we would probably have had to do—we went, again, through Governor King at that point in Massachusetts and requested medicaid approval for Jamie. Since she had been declared disabled, having been in the hospital longer than 70 days, we had petitioned the Department of Public Welfare that she be approved for medicaid funding. Through Governor King's office, the commissioner, Tom Spirto, on October 29, authorized funding for her for that operation.

Mr. **Durbin**. Would that have required some kind of means test, as far as you were concerned, that you would have surrendered a certain amount of your assets, your family assets?

Mr. **Fiske**. No. That is one of the questions that had come up. In Jamie's case, since she had been in the hospital longer than 70 days she, under social security, was declared disabled.

Apart from any assets that we would have as a family, being declared SSI eligible in her case made her eligible for medicaid in Massachusetts. Being eligible for medicaid allowed us to go ahead and petition the commissioner of public welfare to give prior approval to that type of surgery.

The difficulty that that presents with Blue Cross-Blue Shield is that there was no guarantee, even though they put in writing that they would follow through. Also, with medicaid, it is a case-by-case decision.

The problem we had was the time factor. Her surgeon, the day of the surgery, came down the corridor to us, Dr. Najarian, and Dr. Ascher. He looked at us and then he looked down at his hands and said, right after the operation, "Looking at her liver, I would have given her 10 days to live." So, we knew time was running out. He very clearly told us on November 5 that time was 10 days ahead for her dying.

I think we would have had to raise that kind of money in a door-to-door campaign. The citizens of the Commonwealth of Massachusetts, as well as the town of Bridgewater, we never really asked for money. People sent us money in envelopes.

The Governor declared Jamie Fiske Day November 12, for the purposes of offsetting some of those supporting medical costs. Citizens in Minnesota, through Senator Rudy Boschwitz, set up a fund out there to offset some of those living costs, some of the flying back and forth between Boston and Minnesota.

People were extremely generous, their wanting to help us as a family, not only in Massachusetts and Minnesota, but we got letters from as far away as Texas, California, Maine, of people wanting to help by sending money.

It would have involved us petitioning people for that kind of money to take care of it. Again, the obstacle that that presents is the day that Jamie was put on the transplant list, September 29, was the same day that Blue Cross-Blue Shield authorized the payment for that operation.

Mr. **Durbin**. So you had to have the money before you made the list?

Mr. **Fiske**. In true justice to the University of Minnesota, they never held Jamie's health care in ransom. They told us very clearly to secure the funding before we came out, but they never said, we are not going to treat her and send you back home unless that money is in place.

But it is coincidental, though, that they did ask that we get that in writing from Blue Cross-Blue Shield. When she was put on the transplant list was the same day that Blue Cross-Blue Shield did come through.

Mr. **Durbin**. Mrs. Thiel, you testified earlier, and I guess you put it together in a couple words very succinctly, about this tin cup syndrome. We have heard the testimony from Mr. Fiske about what he and his wife faced if they couldn't get the Government approval and if the private insurance company had said no.

The thing that crosses my mind is how many people have the awareness in their own mind of what can be done? How many people are intelligent, have enough drive in a situation with personal adversity that they are going to start searching for the media and looking around? How many are poor and wouldn't know where to start?

I am just wondering if you have any thoughts about that whole tin cup approach and what we ought to do about it.

Mrs. **Thiel**. I think there are very few people that are as sophisticated as the Fiske family and have the contacts and would know what to do. I know that years ago, when my son was diagnosed, I would not have known where to begin.

When these families call, they are really at their rope's end. Some of them have been told that they have to have upfront money of $300,000 before they will even consider evaluating their child. That is a desperate situation. I don't know where I would go for $300,000.

As I say, the only thing that we can do is give them guidance, to talk to your insurance company. You really have to do battle with your insurance company. Don't take no for an answer. Talk to your legislators. See what coverage your carry from medicaid-medicare in your area.

Then, of course, try to get some of the local organizations, the fire department, the junior league, and so forth, some of the civic organizations, to help you to raise that money. This has happened in many areas.

Again, I think as more awareness is created through radio and television programs, that people are doing this. I think that the media has been very, very responsive to the needs of a lot of these families.

Mr. **Durbin**. There have been suggestions, and we have heard them from time to time, about some efforts in the Government, on the Federal and State levels, toward catastrophic insurance, to help families in this particular predicament when the medical bills have gone beyond a certain point and gone beyond the means of most American families.

What do you think of that? Do you have any problems with that in your own mind of embarking on that kind of program, even though we are living in pretty difficult times economically?

Mrs. **Thiel**. We are always looking at the dollars. Of course, liver transplants have come into view much more recently. I don't believe that a kidney transplant is as costly in general as a liver transplantation. But when you consider the value of a life compared to the cost of that liver transplant, I think that there is no question in my mind at all.

Mr. **Durbin**. I knew you would answer that way.

Dr. Ogden, yesterday I mentioned to the panel that when I worked in the Illinois State Senate we adopted the Uniform Anatomical Gift Act. We tried to make some progress with our driver's licenses, to put the consent on the back of a license.

Do you feel that that, aside from increasing public awareness, which I think it has done, has really created a good link between donors and recipients when it comes to organ transfer in your own mind?

Dr. **Ogden**. No, I don't think it has. I think it has increased awareness. In that regard, we are beginning increasingly to see families who, in the appropriate circumstances, request a consideration of donation. The initiative is increasingly coming from the next of kin of the injured person. So, I think it is helping in that indirect sense.

It is rarely that the driver's license is used as the legal document through which transplantation is achieved. It happens, but it is rare.

My particular suggestions were that the recorded wish of an individual on their driver's license be, in fact, noted on admission of anybody to a hospital of significant size, in the hope that, in fact, one that would lead all along the trail the health care team and the individual and family, because if they request the driver's license to record your donor status, immediately you have focused attention on that without saying we want you to make a decision. Now you are sick, we want you to make a decision about whether you want to be a donor I don't think that is appropriate.

I do think that if you have already made that decision, it focuses on it slightly but doesn't make a big deal of it, to say let's see your driver's license and record what is on there. It also would increase the sense of it throughout the hospital. Wherever the patient went, this would basically be recorded. I think in that way we could begin to make use of the driver's license.

By the way, there is no uniformity from State to State about the way in which this is handled. In at least one State you must make a declaration of yes or no. Well, faced with having to say right now whether you want to be a donor or not, most people put no.

In some States it is entirely optional. In some States you are asked whether you want to make a declaration. In other States you aren't asked, but if you ask them, if you would know enough to ask at the driver's license bureau, they would say oh, yes, and then they will pull out an affidavit and record it on there.

Mr. DURBIN. I think that is most people's experience.

Dr. OGDEN. So, there could be room for gaining a greater degree of uniformity about how this is handled, assuming there could be that kind of agreement on a national basis.

Mr. DURBIN. Can I ask you two other questions somewhat related to that in your experience?

Have there been problems related to the definition of brain death, in terms of all States not adopting the same standard, that have resulted in delay or the loss of a donated organ?

Dr. OGDEN. Yes, there has even been active resistance in some States by various facets of the medical community and lack of the ability to come to agreement.

The wording of the uniform brain death law, which has been adopted by 28 States, I believe, seems satisfactory although actually that wording hasn't been adopted by 28 States. Twenty-eight States have a brain death law, not always of the same wording.

I think again this is an area we need to encourage. In some States, declaring a person brain dead is not a legal way to declare death.

There is an opportunity here—perhaps this hasn't been commented on. A brain death law serves more function than simply in organ donation. It establishes criteria by which brain death can be pronounced whether or not organ donation is even a consideration.

If the individual, for instance, is 70 years old, that person is probably not a potential organ donor for any of the organs we have been talking about today. Yet, in the absence of a way to recognize and pronounce brain death, there is a likelihood that the care will be extended beyond that point which might otherwise be necessary, at additional expense.

What I am saying is that a brain death law can be cost effective in terms of not providing unnecessary medical care.

Mr. DURBIN. Thank you very much.

Thank you, Mr. Chairman.

Mr. GORE. The subcommittee just received a communication from LeBonheur Hospital in Memphis that Brandon Hall's condition is good. The prognosis is good, but the condition is critical. They are saying that his chances are 50-50. There was a 12-hour operation. Doctors announce that he suffered cardiac arrest twice during the operation and, as a result, they are cautiously optimistic. I am sure we will be hearing a good deal more from LeBonheur.

If I was asked to summarize the basic purpose of these hearings, Mr. and Mrs. Fiske, it would be this. Parents should not have to go through what you had to go through in order to save the life of Jamie. They should not have to experience what Mrs. Hall had to go through in order to try to save Brandon's life.

There are many Jamie Fiskes and Brandon Halls, and there are going to be many more to come. We need to save them by designing and establishing a national strategy that will help parents in the situation that you found yourselves in, to remove the obstacles of financing, to remove the obstacles in the form of increasing awareness among American citizens about how important organ donation is, and to better organize the organ procurement system nationwide, so we can save these children's lives in the future.

I want to thank all of our witnesses on this first panel for being with us. You have helped us in our effort. We are precisely halfway through our 3 days of hearings. I would like to thank you again for helping us out.

Mr. **Fiske**. Thank you, Mr. Gore.

Mr. **Gore**. Our next panel is made up of Prof. Alexander Morgan Capron, Executive Director of the President's Commission for the study of ethical problems in medicine and biomedical and behavioral research; Dr. Robert Veatch, professor of medical ethics and senior research scholar at the Kennedy Institute of Ethics at Georgetown; and Dr. James Childress, professor of religious studies and professor of medical education in the Department of Religious Studies at the University of Virginia in Charlottesville.

I would like to welcome all three of our witnesses here today. Professor Capron, as Executive Director of the Commission on Bioethics—that is what I call it, rather than its long name—we have had an opportunity to talk with you on several occasions.

As you know, we have the highest regard for the work you have done, and we are honored to have you leading off this panel on the bioethical considerations involved in a national strategy for organ transplantation and organ procurement.

Without objection, your entire prepared statement will be included in the record. Please proceed with your presentation.

STATEMENTS OF ALEXANDER MORGAN CAPRON, EXECUTIVE DIRECTOR, PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH; DR. JAMES CHILDRESS, PROFESSOR OF RELIGIOUS STUDIES AND PROFESSOR OF MEDICAL EDUCATION, DEPARTMENT OF RELIGIOUS STUDIES, UNIVERSITY OF VIRGINIA; AND DR. ROBERT M. VEATCH, PROFESSOR OF MEDICAL ETHICS, SENIOR RESEARCH SCHOLAR, KENNEDY INSTITUTE OF ETHICS, GEORGETOWN UNIVERSITY

Mr. **Capron**. I appreciate the opportunity to testify, in civilian dress, now that the Commission has concluded. From an ethical and legal vantage point, it seems to me that the central question is what should society's response be to the need of tens of thousands of Americans for complex and expensive forms of treatment for grave illnesses, particularly when the treatment draws on limited resources and, though of demonstrated value, is still partially experimental.

Because of the lateness of the hour, I want to abbreviate very much what I have to say and offer an opportunity for any questions. I divided my observations into those which deal with the scarcity of organs and the scarcity of funds.

SCARCITY OF ORGANS

Looking first at the question of cadaver organs, there are three issues: First, the lingering uncertainty about the determination of death, which we just heard about in the exchange with Mr. Durbin; second, the lack of adequate donations; and third, the inadequate coordination of the organ donor process. Let me make a few observations on these.

You are familiar with the work of the President's Commission on the Determination of Death, and I have summarized that in an attachment to my statement. The Commission, along with the National Conference of Commissioners on Uniform State Laws, the American Bar Association, and the American Medical Association, recommends the adoption of the Uniform Determination of Death Act. That law is now effective in 14 jurisdictions. We are waiting still for congressional action on that, which was contemplated in the 97th Congress, and might happen in the 98th, to cover Federal jurisdictions and as a spur to State adoption.

The Commission strongly recommended that the adoption of the statute be kept separate from the Uniform Anatomical Gift Act, which is law in all 50 States and the District of Columbia, because the two subjects, although linked, are not coterminous.

The second question, which deals with the inadequacy of the supply of organs, relates to the fact that despite the comments that were just made by the representative of the Kidney Foundation, I do not believe that we know what part of the population has taken steps to make an inter vivos gift, an intention to give a gift, that is, under the Uniform Anatomical Gift Act.

Several alternatives for increasing donation above the level which now exists would involve changes in the law. The first would be going to a system of payment either made to a person during the lifetime to be binding at the time of death, or made to relatives. Given our poor history with the sale of organs, such as blood, already I believe most commentators in this field view a movement toward a marketplace in organs as an unfortunate step. Certainly most physicians object very strongly to this.

Mr. **Gore**. You see no evidence of that, do you?

Mr. **Capron**. One sees evidence of it from time to time—ads in newspapers offering organs, kidneys, corneas, things like this—but I think it is a very unusual thing still because most physicians don't want to participate.

Of course, a seller and buyer could engage in an arrangement independent of the knowledge of the physicians involved. It is not unusual when there has been a true donation for the donor to have medical expenses paid. There is a fine line between paying medical expenses and paying time off from work, if you are talking about a live donor, and so forth, or expenses of the funeral, if you are talking about a deceased donor. So, there is a shading between a market system and a donation system.

The major objection, I think, is that the present system, which involves a gift relationship, has certain important values for society irrespective of the practical question of whether one would, as in the blood area, end up with organs that were less suitable than from a system of unpaid donations. For one thing, if you turn something into a market, the incentive for other people to be altruistic to make a donation seems to be decreased.

A second alternative at the opposite extreme would be an option of statutes allowing the State to take organs on a compulsory basis without consent as a routine matter, on the grounds that organs are valuable resources that a deceased person should not be allowed to destroy. In my reading of constitutional law, it would appear to require a high-level justification for such a taking, even from cadaver donor bodies.

Mr. GORE. No one has recommended that one, have they?

Mr. CAPRON. Oh, yes, it has been recommended. In 1968 there was a recommendation to that effect, a law journal article detailing that. That is all in my materials that I provided to the committee.

Mr. GORE. Thank you.

Mr. CAPRON. The third is replacing what we now have, which is sometimes referred to as an opting-in or contracting-in system, with an opting or contracting out system; that is to say, to begin with the presumption that everyone would want to donate and then permit people during their life to indicate that they do not want to be included.

One suggestion to that effect was made by Prof. Jesse Dukeminier of UCLA in 1968. The problem with his suggestion was that he would also allow the relatives to object after death. The major impediment to the use of organs at the moment is the uncertainty that surrounds the point of donation: Has the person made a choice? What are the relatives' wishes? Can the relatives be contacted in time? Does one feel comfortable intruding upon their grief by discussing this subject with them?

If we were to have an opting-out system, that included relatives, as Dukeminier proposed, I don't think we would gain anything. If you had an opting-out system which only relied on the individual's own choice, it would seem to me to be very probable that we would gain in terms of the number of organs because public opinion polls done on this subject for the last 15 years have shown that the public by overwhelming numbers, 70 to 80 percent favor donations and would wish to make a donation. Yet, we know that only some far lower proportion of people actually fill out the cards during their lifetime—though I don't know anyone who has good statistics on this, despite statements that are made.

All of these alternatives deserve some exploration, but I for the moment would think that we need to give greater emphasis, as the previous panel told you, to increasing donations under our present system.

I think we have an excellent legal framework in the Uniform Anatomical Gift Act [UAGA] and the Uniform Determination of Death Act for donations. What we need is greater public information and education, to make people aware of this as something which they ought to do during their lifetime to avoid the grieving situation for their family.

I would, therefore, urge you to lend your support to efforts by private, State and Federal groups to publicize the UAGA so as to preserve the great ethical as well as social values in voluntary donation. If that is judged inadequate to obtain needed organs for transplantation, I suggest at most an amendment of the UAGA to make donation automatic unless a person opts out during his or her lifetime.

The third issue about donation from cadaver organs is the need for sharing of organs. Scarcity at the moment breeds a proprietary attitude toward organs among those who, in the term of art, "harvest" them. Even with kidneys, the attitude has been that the hospital at which the procedure is done will typically say we will keep one for one of "our" patients and put the other one into the system.

The problem with this is that for a good match—and the better the match, even with present immunosuppressive agents, the better the likelihood of a good survival—you need to increase the pool of recipients and donors being compared with each other on a tissue-typing basis.

Furthermore, it contradicts notions of fairness as well as good sense when organ availability depends upon the ability of particular recipients or their family members to generate publicity for their plight. You can imagine that the news media are really not that interested after the first Jamie Fiske story and the second, third, fourth, and fifth liver transplant. The interest dies down. It seems to me that the spectacle, whatever cathartic function it may serve for the public once a donor is found, is contrary to our usual norms of the proper way in which medical care should be delivered.

Depending upon logistical considerations, I believe that a regional or national system of organ transfers would be advisable, with support by local coordinators to facilitate the actual donations. I believe you should endorse surveillance and coordination by the CDC in this field.

I won't elaborate in my comments now on my prepared remarks on living donors. It is a more minor issue. The case that came up recently in Iowa, it seems to me, was an unfortunate one and I hope that that decision by the judge is reversed on appeal, so that people understand that their participation in this system will be judged by the usual norms of confidentiality and they will not be subject to the kind of pressure that the judge apparently decided was suitable on that woman as a bone marrow donor.

SCARCITY OF FUNDS

The scarcity of funds raises a problem which we see now throughout medical care. The ethical issues posed for public and private decisionmakers are those that arise whenever scarcity is involved, which are the questions of the societal obligation and of fairness.

My two basic conclusions in this area are, first, that the issue is not how to avoid making difficult choices among people in need by throwing more money at the problem, but rather how to make such choices in a justifiable manner; and second, I conclude that we must develop means for determining how new medical developments relate to society's obligation to insure equitable access to an adequate level of care.

The availability of reimbursement through medicare's special entitlement for end-stage renal disease hasn't ended our ethical problems there. Physicians, nurses, hospital administrators still have to agonize over cases, asking whether a particular treatment should be used with a particular patient. Moreover, it is quite obvious by now that we cannot say "yes" to funding every treatment. We must instead make sure that we don't say "no" unfairly.

In addressing the issue of society's ethical obligation toward health care, the President's Commission determined that the standard of equity requires that everyone have access to an adequate level of care without the imposition of excessive burdens.

Defining adequacy is clearly a difficult task. To eliminate repetition on this point, I have set forth the Commission's discussion in one of the appendices to my statement.

Of greatest relevance here are two points: First, while judgments about whether a particular treatment are not solely matters for professional judgment, expertise of the sort that the National Center for Health Care Technology in HHS was beginning to develop before it was abolished, regarding the reimbursement under Federal health care financing programs, could certainly be very valuable.

Second, since the greatest test of fairness will probably be comparability, decisionmakers, particularly those in the public sector whose decisions are likely to be generalized, must keep in mind the tendency of limited acts of generosity to have very broad ramifications.

I urge that you explore with HHS its ability to assess the relationship of particular treatments, not just organ transplantation, to the adequate level of health care that should be guaranteed by society to its members in a manner that is fair and consistent.

I regret, Mr. Chairman, I think as you and your staff knew, I have an obligation to teach a class. I have 125 students waiting. With the indulgence of my copanelists, I would welcome your questions now, Mr. Chairman.

[The statement of Mr. Capron follows:]

STATEMENT OF ALEXANDER MORGAN CAPRON, PROFESSOR OF LAW, ETHICS AND PUBLIC POLICY, GEORGETOWN UNIVERSITY LAW CENTER

ETHICAL AND LEGAL ISSUES IN ORGAN REPLACEMENT

Good morning, Mr. Chairman and members of the Subcommitte, and thank you for inviting me to address some of the legal and ethical issues in organ transplantation. I applaud your decision to take up this important and timely topic and hope that my remarks will be helpful in your explorations.

As the chairman has already mentioned, I was until just recently the director of a presidential commission that studied a wide range of bioethical problems. Although I will draw on the work of that commission in portions of what I have to say today, I am not speaking on behalf of the Commissioners. Indeed, while a number of the 11 reports of the President's Commission touch on today's topic, the Commission did not study the subject directly.

From an ethical and legal vantagepoint, the central question as I see it is: what should society's response be to the need of tens of thousands of Americans for complex and expensive forms of treatment for grave diseases (usually chronic in nature but also imminently life-threatening), particularly when the treatment draws on limited resources and, though of demonstrated value, is still partially experimental? That is a complex question which, I believe, captures most of the issues I'd like to address.

I. SCARCITY: ORGANS

You have already heard, yesterday and earlier this morning, about the numbers of patients with kidney, heart, liver, or lung conditions who might benefit from organ transplantation or mechanical substitution. I would like first to discuss the issues raised by their need for organs for transplantation. In the case of most organs, the only source is a cadaver; in the case of kidneys, as for bone marrow and blood products, there are two sources for such organs: living donors as well as cadavers. These two sources raise somewhat different issues.

A. Cadavers

Under the Uniform Anatomical Gift Act (UAGA)--the most successful act, in term of uniform adoption, of any proposed by the NCCUSL--a simple and effective method already exists in every state for the donation of cadaver organs. If organs were obtained for transplantation from all people who die each year under circumstances that would make them suitable organ donors (and if these organs were then distributed in an efficient fashion), there would be more than sufficient supply for present estimates of need and medical capability. Unfortunately, this is not now the case for several reasons: (1) lingering uncertainty about the legal "definition" of death; (2) lack of adequate donations, by people during their own life or by their relatives after the patients' death; and (3) inadequate coordination, locally, regionally and nationally.

1. "Definition" of Death

The first statutorily mandated subject addressed by the President's Commission was the "definition" of death. This subject is, as you know, relevant to organ transplantation, because to maximize their potential benefit to recipients, organs should removed as quickly after the donor has died as possible, preferably while they continue to be nourished by oxygenated blood circulating as a result of artificial support of the deceased's heart and lungs.

For the sake of brevity, I have appended to these remarks the summary of our conclusions from the opening pages of the July 1981 report Defining Death (Attachment A). The two points most relevant here are: first, that the Commission, along with three other leading groups, recommended adoption of the Uniform Determination of Death Act (UDDA), which is now law in 14 jurisdictions, including the District of Columbia, although consideration of an enactment for areas under federal jurisdiction, which was expected in the 97th Congress, never occurred; and second, that the Commission urged that the UDDA be kept separate from the UAGA. Although it was the advent of heart transplantation that brought the issue of "defining" death to the public's attention--and, indeed, that prompted the medical profession's attention to the conclusions of the 1968 Harvard *Ad Hoc* Committee (205 *J.A.M.A.* 337)--the need to update the legally recognized standards for determining that someone has died does not rest primarily on any need to facilitate organ transplantation but on the confusion created for the old heart-lung standard by the use of modern forms of treatment that can simulate the traditional "vital signs" in patients who are actually dead. (*See* Attachment B for excerpts from the Commission's report on this point.)

Most American jurisdictions now have some form of modern "definition" of death. Greater public and professional certainty on the issue would be provided if the UDDA were adopted in all jurisdictions, and if those people--principally physicians and public officials concerned with health issues--who educate the public on such matters were to be careful with their terms, so as not to perpetuate any lingering sense of "two kinds" of death (*i.e.*, one for organ donors, the other for the "truly dead") or of a "dead body" being maintained by "life support" equipment, and so forth. The reliability of modern medical criteria for determining that death has occurred is manifested by the guidelines of the Commision's medical consultants (Attachment C), which the *Journal of the American Medical Association* hailed as a "landmark" event.

I urge you to provide leadership on this issue, both through Congressional action on the UDDA and, even more important, through encouragement to the states to enact the UDDA.

2. *Inadequate Donations*

Public polls have consistently found that an overwhelming majority of Americans favor organ donation, yet only a proportion of the population--the exact figure is, to the best of my knowledge, unknown--has availed itself of simple procedures of the UAGA. A larger number of donations occur because the UAGA also permits specified relatives to donate the organs of a dead person who did not make a decision to so so during his or her lifetime; these choices are frequently complicated by having to be made in the context of the relatives' grief (and often shock) over the death of person, which has typically occurred suddenly and often violently.

In a book written a decade ago, Catastrophic Diseases: Who Decides What?, Dr. Jay Katz of Yale and I considered a number of alternatives to the UAGA, including a payment procedure, "opting-out" in place of "opting-in," or compulsory removal of suitable organs. From an ethical and social vantagepoint, all of these alternatives have the disadvantage of turning what is now part of a "gift relationship" into a "taking" or "sale"--but such considerations might be overridden if voluntary donations do not produce socially satisfactory results. (Again, for the sake of brevity, excerpts from our book are appended as Attachement D.) Since that time, some states have attempted to increase participation by linking the "donor card" in several ways with driver licensure; however, it does not appear that adequate studies of various methods--much less vigorous educational efforts--have been generally undertaken. If we are to move beyond the UAGA, I continue to believe that a pure form of "opting-out"--rather than the proposal made in 1968 by Professors Dukeminier and Sanders (279 New England J. Med. 413), under which next-of-kin could also object to removal of the organ--would be the next best alternative.

I urge you to lend your support to efforts by private, state and federal groups to publicize the UAGA, so as to preserve the great ethical as well as social values in voluntary donation; if that is judged inadequate to obtain needed organs for transplantation, I suggest the amendment of the UAGA to make "donation" automatic unless a person "opts out" during his or her lifetime.

3. Inadequate Coordination

The scarcity of organs makes them very dear; the burdens imposed in obtaining organs, including the burden of going to a grieving family to ask permission, increase the tendency to treat them as a resource of the local facility. Yet any limitations on the widest possible sharing of organs among transplant groups is medically unfortunate. Despite improved methods of fighting rejection, a better "tissue match" increases the likelihood of success, and the wider the pool of donors and recipients, the greater the likelihood of a good "match." (See Attachment E.) Certainly, it contradicts notions of fairness as well as good sense when organ availability depends upon the ability of particular recipients or their family members to generate publicity for their plight; moreover, this spectacle--while serving a cathartic function for the public if someone comes forward with an organ to relieve a patient's desperate plight--is contrary to our usual proper norms of medical privacy and human dignity.

Depending on logistical considerations, I believe that a regional or national system of organ transfers would be advisable, with support for local coordinators to facilitate donations. You should encourage surveillance and coordination by the CDC in this field.

B. Live Donors

The use of living donors raises a number of serious issues primarily centered around voluntary, informed consent (see second part of Attachment D infra). The major issue needing continued attention is that of the participation of minors as donors (primarily of bone marrow) for their relatives.

Another concern--the social expectation of privacy and voluntariness in organ donation--was drawn into question by a recent case in Iowa, in which a man with leukemia was attempting to learn from the state university hospital the identity of a woman whose tissue type was known by the hospital to be a good match for an experimental bone marrow graft to treat his leukemia. The Institutional Review Board had shown, in my view, appropriate sensitivity to the ethical questions in the way that it had permitted the physician-investigator to inquire in a nonspecific way whether the woman (who had been "typed" as part of an attempted treatment of her own child's leukemia) would be willing to consider donating bone marrow to patient-subjects in experimental treatments. It is regrettable that the trial judge insisted that she be recontacted with the specifics of the instant patient's needs; the case is now on appeal.

II. SCARITY: FUNDS

The need for organs for transplantation makes this field somewhat unusual--but the expense of transplantation, like that of mechanical replacement for failed organs, raises questions that assert themselves with increasing urgency in the health arena. The ethical issues posed for public and private decisionmakers are those that arise whenever scarce funds are at issue, namely issues of obligation and of fairness. My two basic conclusions in this area are (1) that the issue is not how to avoid making difficult choices among people in need but rather how to make such choices in a justifiable manner, and (2) that we must develop better means of determining how new medical developments relate to society's obligation to ensure equitable access to health care.

A. Making Choices

A decade ago the federal government did an extraordinary thing: in the face of the suffering and death of a majority of the patients with end-stage renal disease (numbering in the thousands) who could not obtain treatment (principally, hemodialysis) that had already been shown effective in sustaining life and restoring "normal" functioning, Congress amended the Medicare law to guarantee federal funding of therapy for this single disease entity. (The Commission reviewed this history briefly, as an example of the theme of "limited resources" in its final report; see Attachment F.)

What have we learned from this experience? First, that the predictions of the cost of such programs are very unreliable. While we ought not to overgeneralize from that experience--since the particular legislation was enacted without a detailed examination that might have produced somewhat more accurate forecasts of costs--we ought also not forget it. Demand tends to rise well above projections, particularly when medical and institutional prestige, and personal and corporate profits, are playing a role in determining "demand."

Second, and more important, we have learned that money is only briefly effective as a "cure" to relieve our collective discomfort over having to make moral choices, particularly choices that appear to be God-like: "who will live and who will die?" Although the funds are now available to treat chronic renal failure in any patient, physicians, nurses and health administrators must draw a line somewhere--not as the British health system does, based upon age, but upon a combination of factors. For example, in reporting last month on Deciding to Forego Life-Sustaining Treatment, the President's Commission stated that because the benefit to the patient would be so small, it would be "very hard to justify dialysis for a permanently unconscious patient who develops kidney failure" (p. 190).

Although the line of "no benefit" is a clear one, difficulties of choice persist when particular patients in need are indentified; it then becomes very difficult to deny any life-supporting treatment of possible benefit. But we must--and perhaps at the level of statistical risk and so forth, we will be able to--draw some line, unless we are prepared to say patients are guaranteed access to any and all care they want, "need," or might possible profit from receiving.

B. Equitable Access

In addressing this issue of society's ethical obligation toward the health care of its members, the Commission determined that the standard of equity requires that everyone have access to an adequate level of care without the imposition of excessive burdens. Defining "adequacy" is clearly a difficult task, and to eliminate repetition, I have set forth the Commission's discussion of this point, in Securing Access to Health Care, as Attachment G to this statement. Of greatest relevance here are two points: first, while judgments about whether a particular treatment are not solely matters for professional judgment, expertise of the sort that the National Center for Health Care Technology (in HHS) was beginning to develop (regarding reimbursement under federal health care financing programs) certainly could be valuable; and second, since the greatest test of fairness will probably be "comparability," decisionmakers (particularly those who operate publicly, whose judgments are thus most likely to be treated as being generally applicable) must keep in mind the tendency of limited acts of generosity to have very broad ramifications.

> I urge that you explore the ability of HHS to assess the relationship of particular treatments--not just organ transplantation--to the adequate level of health care that should be guaranteed by society to its members in a manner that is fair and consistent.

Capron 4/14/83

ATTACHMENT A

Excerpts from

Defining Death

A Report on the
Medical, Legal and
Ethical Issues in the
Determination of Death

July 1981

President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research

1

Summary of Conclusions and Recommended Statute

The enabling legislation for the President's Commission directs it to study "the ethical and legal implications of the matter of defining death, including the advisability of developing a uniform definition of death."[1] In performing its mandate, the Commission has reached conclusions on a series of questions which are the subject of this Report. In summary, the central conclusions are:

1. That recent developments in medical treatment necessitate a restatement of the standards traditionally recognized for determining that death has occurred.

2. That such a restatement ought preferably to be a matter of statutory law.

3. That such a statute ought to remain a matter for state law, with federal action at this time being limited to areas under current federal jurisdiction.

4. That the statutory law ought to be uniform among the several states.

5. That the "definition" contained in the statute ought to address general physiological standards rather than medical criteria and tests, which will change with advances in biomedical knowledge and refinements in technique.

6. That death is a unitary phenomenon which can be accurately demonstrated either on the traditional grounds of irreversible cessation of heart and lung functions or on the basis of irreversible loss of all functions of the entire brain.

7. That any statutory "definition" should be kept separate and distinct from provisions governing the donation of cadaver organs and from any legal rules on decisions to terminate life-sustaining treatment.

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[1] 42 U.S.C. §1802 (1978).

To embody these conclusions in statutory form the Commission worked with the three organizations which had proposed model legislation on the subject. the American Bar Association, the American Medical Association, and the National Conference of Commissioners on Uniform State Laws. These groups have now endorsed the following statute, in place of their previous proposals:

> **Uniform Determination of Death Act**
>
> An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

The Commission recommends the adoption of this statute in all jurisdictions in the United States.

ATTACHMENT B

Excerpts from

Defining Death

A Report on the
Medical, Legal and
Ethical Issues in the
Determination of Death

July 1981

President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research

Uniformity Among People and Situations: Besides moving slowly, the law ought to move evenhandedly. The statute ought not to reinforce the misimpression that there are different "kinds" of death, defined for different purposes, and hence that some people are "more dead" than others.

In many contexts, definitions are handmaidens to other purposes lawmakers are seeking to achieve. Rather than asking "what is death"? one might ask, "what difference does it make whether somebody is dead"?[4] That question has many answers, most of them familiar to everyone. Criminal law (murder v. aggravated assault), tort law (wrongful death), family law (the status of spouse and children), property and estate law, insurance law (payment of life insurance benefits and termination of health insurance payments), and tax law, as well as some actions and culturally determined behaviors of family members, physicians, clerics and undertakers are all initiated by the determination that a death has occurred. Were there good reason for one branch or another of the law or one or another cultural institution to employ a different "definition" of death, logic would not preclude such a step. But in fact, society has found it desirable to employ a single standard for declaring death in all these circumstances and no special-purpose definitions have been seriously advanced. Calling the same person "dead" for one purpose and "alive" for another would engender nothing but confusion.[5] Thus, in setting forth the law in statutory form, the wisest and most cautious course (furthering the principle of incrementalism as well) would be to adopt a rule recognizing the unity of the concept of death. Such a "definition" of death can be applied in all appropriate circumstances; if a special need is identified for acting on a different basis, a separate status—other than that of being "dead"—could be defined for that purpose.[6]

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[4] Roger B. Dworkin, "Death in Context," 48 *Ind. L. J.* 623, 629 (1973).

[5] See, e.g. Fred Fabro, "Bacchiochi vs. Johnson Memorial Hospital".45 *Conn. Med.* 267 (1981) chronicling the troublesome case of Melanie Bacchiochi. On February 11, 1981 after repeated clinical examinations confirmed by electroencephalography, physicians found she had suffered irreversible loss of total brain function. Her physician was unwilling to remove her from the respirator because of legal uncertainty since Connecticut's statute on "brain death" applies only to organ transplantation. "It is ironic that if the patient had been a donor, she could have been pronounced dead on February 11 and the respirator could have been withdrawn. Dead for transplantation, but not dead otherwise!" *Id.* at 268.

[6] Alexander M. Capron, "The Purpose of Death: A Reply to Professor Dworkin," 48 *Ind. L.J.* 640, 643–45 (1973); Capron and Kass, *op cit.* at 107–08.

* * *

Finally, since the proposed statute is intended to apply in all situations, it ought not to be incorporated into a state's Uniform Anatomical Gift Act (UAGA). Placing it there would create the mistaken impression that a special "definition" of death needs to be applied to organ transplantation, which is not the case. (As a matter of fact, most of the respirator-supported cases in which the brain-oriented standard would be applicable are not potential donors, as noted in Chapter 2.) Section 7(b) of the UAGA makes the time of death a matter to be determined by the attending physician; the proposed Uniform Determination of Death Act specifies the grounds on which such a determination are made. Some people have expressed concern that a determination of death in a potential organ donor might be made by a physician with a conflict of interest, but the UAGA specifies that the physician who determines that death has occurred "shall not participate in the procedures for removing or transplanting a part."[66]

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[66] Uniform Anatomical Gift Act § 7(b), 8 *Uniform Laws Annot.* 6C8 (1972).

ATTACHMENT C

Special Communication

Guidelines for the Determination of Death

Report of the Medical Consultants on the Diagnosis of Death to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

The guidelines set forth in this report represent the views of the signatories as individuals; they do not necessarily reflect the policy of any institution or professional association with which any signatory is affiliated. Although the practice of individual signatories may vary slightly, signatories agree on the acceptability of these guidelines. Jesse Barber, MD; Don Becker, MD; Richard Behrman, MD, JD; Donald R. Bennett, MD; Richard Beresford, MD, JD; Reginald Bickford, MD; William A. Black, Jr, MD; Benjamin Boshes, MD, PhD; Philip Braunstein, MD; John Burroughs, MD, JD; Russell Butler, MD; John Caronna, MD; Shelley Chou, MD, PhD; Kemp Clark, MD; Ronald Cranford, MD; Michael Earnest, MD; Albert Ehle, MD; Jack M. Fein, MD; Sal Fiscina, MD, JD; Terrance G. Furlow, MD, JD; Eli Goldensohn, MD; Jack Grabow, MD; Philip M. Green, MD; Ake Grenvik, MD; Charles E. Henry, PhD; John Hughes, MD, PhD, DM; Howard Kaufman, MD; Robert King, MD; Julius Korein, MD; Thomas W. Langfitt, MD; Cesare Lombroso, MD; Kevin M. McIntyre, MD, JD; Richard L. Masland, MD; Don Harper Mills, MD, JD; Gaetano Molinari, MD; Byron C. Pevehouse, MD; Lawrence H. Pitts, MD; A. Bernard Pleet, MD; Fred Plum, MD; Jerome Posner, MD; David Powner, MD; Richard Rovit, MD; Peter Safar, MD; Henry Schwartz, MD; Edward Schlesinger, MD; Roy Selby, MD; James Snyder, MD; Bruce F. Sorenson, MD; Cary Suter, MD; Barry Tharp, MD; Fernando Torres, MD; A. Earl Walker, MD; Arthur Ward, MD; Jack Whisnant, MD; Robert Wilkus, MD; and Harry Zimmerman, MD.

The preparation of this report was facilitated by the President's Commission but the guidelines have not been passed on by the Commission and are not intended as matters for governmental review or adoption.

THE ADVENT of effective artificial cardiopulmonary support for severely brain-injured persons has created some confusion during the past several decades about the determination of death. Previously, loss of heart and lung functions was an easily observable and sufficient basis for diagnosing death, whether the initial failure occurred in the brain, the heart and lungs, or elsewhere in the body. Irreversible failure of either the heart and lungs or the brain precluded the continued functioning of the other. Now, however, circulation and respiration can be maintained by means of a mechanical respirator and other medical interventions, despite a loss of all brain functions. In these circumstances, we recognize as dead an individual whose loss of brain functions is complete and irreversible.

For editorial comment see p 2194.

To recognize reliably that death has occurred, accurate criteria must be available for physicians' use. These now fall into two groups, to be applied depending on the clinical situation. When respiration and circulation have irreversibly ceased, there is no need to assess brain functions directly. When cardiopulmonary functions are artificially maintained, neurological criteria must be used to assess whether brain functions have ceased irreversibly.

More than half of the states now recognize, through statutes or judicial decisions, that death may be determined on the basis of irreversible cessation of all functions of the brain. Law in the remaining states has not yet departed from the older, common-law view that death has not occurred until "all vital functions" (whether or not artificially maintained) have ceased. The language of the statutes has not been uniform from state to state, and the diversity of proposed and enacted laws has created substantial confusion. Consequently, the American Bar Association, the American Medical Association, the National Conference of Commissioners on Uniform State Laws, and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research have proposed the following model statute, intended for adoption in every jurisdiction:

UNIFORM DETERMINATION OF DEATH ACT

> **An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.**

This wording has also been endorsed by the American Academy of Neurology and the American Electroencephalographic Society.

The statute relies on the existence of "accepted medical standards" for determining that death has occurred. The medical profession, based on carefully conducted research and extensive clinical experience, has found that death can be determined reliably by either cardiopulmonary or neurological criteria. The tests used for determining cessation of brain functions have changed and will continue to do so with the advent of new research and technologies. The "Harvard criteria" (*JAMA* 1968;205:337-340) are widely accepted, but advances in recent years have led to the proposal of other criteria. As an aid to the implementation of the proposed uniform statute, we provide here one statement of currently accepted medical standards.

INTRODUCTION

The criteria that physicians use in

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determining that death has occurred should (1) eliminate errors in classifying a living individual as dead; (2) allow as few errors as possible in classifying a dead body as alive; (3) allow a determination to be made without unreasonable delay; (4) be adaptable to a variety of clinical situations; and (5) be explicit and accessible to verification.

Because it would be undesirable for any guidelines to be mandated by legislation or regulation or to be inflexibly established in case law, the proposed Uniform Determination of Death Act appropriately specifies only "accepted medical standards." Local, state, and national institutions and professional organizations are encouraged to examine and publish their practices.

The following guidelines represent a distillation of current practice in regard to the determination of death. Only the most commonly available and verified tests have been included. The time of death recorded on a death certificate is at present a matter of local practice and is not covered in this document.

These guidelines are advisory. Their successful use requires a competent and judicious physician, experienced in clinical examination and the relevant procedures. All periods of observation listed in these guidelines require the patient to be under the care of a physician. Considering the responsibility entailed in the determination of death, consultation is recommended when appropriate.

The outline of the criteria is set forth below in boldface letters. The lightface text that follows each heading explains its meaning. In addition, the two sets of criteria (cardiopulmonary and neurological) are followed by a presentation of the major complicating conditions: drug and metabolic intoxication, hypothermia, young age, and shock. It is of paramount importance that anyone referring to these guidelines be thoroughly familiar with the entire document, including explanatory notes and complicating conditions.

THE CRITERIA FOR DETERMINATION OF DEATH

An individual presenting the findings in *either* section A (cardiopulmonary) or section B (neurological) is dead. In either section, a diagnosis of death requires that *both* cessation of functions, as set forth in subsection 1, *and* irreversibility, as set forth in subsection 2, be demonstrated.

A. An individual with irreversible cessation of circulatory and respiratory functions is dead.

1. *Cessation* is recognized by an appropriate clinical examination.

Clinical examination will disclose at least the absence of responsiveness, heartbeat, and respiratory effort. Medical circumstances may require the use of confirmatory tests, such as an ECG.

2. *Irreversibility* is recognized by persistent cessation of functions during an appropriate period of observation and/or trial of therapy.

In clinical situations where death is expected, where the course has been gradual, and where irregular agonal respiration or heartbeat finally ceases, the period of observation following the cessation may be only the few minutes required to complete the examination. Similarly, if resuscitation is not undertaken and ventricular fibrillation and standstill develop in a monitored patient, the required period of observation thereafter may be as short as a few mintues. When a possible death is unobserved, unexpected, or sudden, the examination may need to be more detailed and repeated over a longer period, while appropriate resuscitative effort is maintained as a test of cardiovascular responsiveness. Diagnosis in individuals who are first observed with rigor mortis or putrefaction may require only the observation period necessary to establish that fact.

B. An individual with irreversible cessation of all functions of the entire brain, including the brain stem, is dead. The "functions of the entire brain" that are relevant to the diagnosis are those that are clinically ascertainable. Where indicated, the clinical diagnosis is subject to confirmation by laboratory tests, as described in the following portions of the text. Consultation with a physician experienced in this diagnosis is advisable.

1. *Cessation* is recognized when evaluation discloses findings of a *and* b:

a. Cerebral functions are absent, and . . .

There must be deep coma, that is, cerebral unreceptivity and unresponsivity. Medical circumstances may require the use of confirmatory studies such as an EEG or blood-flow study.

b. brain stem functions are absent.

Reliable testing of brain stem reflexes requires a perceptive and experienced physician using adequate stimuli. Pupillary light, corneal, oculocephalic, oculovestibular, oropharyngeal, and respiratory (apnea) reflexes should be tested. When these reflexes cannot be adequately assessed, confirmatory tests are recommended.

Adequate testing for apnea is very important. An accepted method is ventilation with pure oxygen or an oxygen and carbon dioxide mixture for ten minutes before withdrawal of the ventilator, followed by passive flow of oxygen. (This procedure allows Pa_{CO_2} to rise without hazardous hypoxia.) Hypercarbia adequately stimulates respiratory effort within 30 seconds when Pa_{CO_2} is greater than 60 mm Hg. A ten-minute period of apnea is usually sufficient to attain this level of hypercarbia. Testing of arterial blood gases can be used to confirm this level. Spontaneous breathing efforts indicate that part of the brain stem is functioning.

Peripheral nervous system activity and spinal cord reflexes may persist after death. True decerebrate or decorticate posturing or seizures are inconsistent with the diagnosis of death.

2. *Irreversibility* is recognized when evaluation discloses findings of a *and* b *and* c:

a. The cause of coma is established and is sufficient to account for the loss of brain functions, and . . .

Most difficulties with the determination of death on the basis of neurological criteria have resulted from inadequate attention to this basic diagnostic prerequisite. In addition to a careful clinical examination and investigation of history, relevant knowledge of causation may be acquired by computed tomographic scan, measurement of core temperature, drug screening, EEG, angiography, or other procedures.

b. the possibility of recovery of any brain functions is excluded, and . . .

The most important reversible conditions are sedation, hypothermia, neuromuscular blockade, and shock.

In the unusual circumstance where a sufficient cause cannot be established, irreversibility can be reliably inferred only after extensive evaluation for drug intoxication, extended observation, and other testing. A determination that blood flow to the brain is absent can be used to demonstrate a sufficient and irreversible condition.

c. the cessation of all brain functions persists for an appropriate period of observation and/or trial of therapy.

Even when coma is known to have started at an earlier time, the absence of all brain functions must be established by an experienced physician at the initiation of the observation period. The duration of observation periods is a matter of clinical judgment, and some physicians recommend shorter or longer periods than those given here.

Except for patients with drug intoxication, hypothermia, young age, or shock, medical centers with substantial experience in diagnosing death neurologically report no cases of brain functions returning following a six-hour cessation, documented by clinical examination and confirmatory EEG. In the absence of confirmatory tests, a period of observation of at least 12 hours is recommended when an irreversible condition is well established. For anoxic brain damage where the extent of damage is more difficult to ascertain, observation for 24 hours is generally desirable. In anoxic injury, the observation period may be reduced if a test shows cessation of cerebral blood flow or if an EEG shows electrocerebral silence in an adult patient without drug intoxication, hypothermia, or shock.

Confirmation of clinical findings by EEG is desirable when objective documentation is needed to substantiate the clinical findings. Electrocerebral silence verifies irreversible loss of cortical functions, except in patients with drug intoxication or hypothermia. (Important technical details are provided in "Minimal Technical Standards for EEG Recording in Suspected Cerebral Death" [*Guidelines in EEG 1980*. Atlanta, American Electroencephalographic Society, 1980, section 4, pp 19-24].) When joined with the clinical findings of absent brain stem functions, electrocerebral silence confirms the diagnosis.

Complete cessation of circulation to the normothermic adult brain for more than ten minutes is incompatible with survival of brain tissue. Documentation of this circulatory failure is therefore evidence of death of the entire brain. Four-vessel intracranial angiography is definitive for diagnosing cessation of circulation to the entire brain (both cerebrum and posterior fossa) but entails substantial practical difficulties and risks. Tests are available that assess circulation only in the cerebral hemispheres, namely radioisotope bolus cerebral angiography and gamma camera imaging with radioisotope cerebral angiography. Without complicating conditions, absent cerebral blood flow as measured by these tests, in conjunction with the clinical determination of cessation of all brain functions for at least six hours, is diagnostic of death.

COMPLICATING CONDITIONS

A. Drug and Metabolic Intoxication.—Drug intoxication is the most serious problem in the determination of death, especially when multiple drugs are used. Cessation of brain functions caused by the sedative and anesthetic drugs, such as barbiturates, benzodiazepines, meprobamate, methaqualone, and trichloroethylene, may be completely reversible even though they produce clinical cessation of brain functions and electrocerebral silence. In cases where there is any likelihood of sedative presence, toxicology screening for all likely drugs is required. If exogenous intoxication is found, death may not be declared until the intoxicant is metabolized or intracranial circulation is tested and found to have ceased.

Total paralysis may cause unresponsiveness, areflexia, and apnea that closely simulates death. Exposure to drugs such as neuromuscular blocking agents or aminoglycoside antibiotics, and diseases like myasthenia gravis are usually apparent by careful review of the history. Prolonged paralysis after use of succinylcholine chloride and related drugs requires evaluation for pseudocholinesterase deficiency. If there is any question, low-dose atropine stimulation, electromyogram, peripheral nerve stimulation, EEG, tests of intracranial circulation, or extended observation, as indicated, will make the diagnosis clear.

In drug-induced coma, EEG activity may return or persist while the patient remains unresponsive, and therefore the EEG may be an important evaluation along with extended observation. If the EEG shows electrocerebral silence, short latency auditory or somatosensory-evoked potentials may be used to test brain stem functions, since these potentials are unlikely to be affected by drugs.

Some severe illnesses (eg, hepatic encephalopathy, hyperosmolar coma, and preterminal uremia) can cause deep coma. Before irreversible cessation of brain functions can be determined, metabolic abnormalities should be considered and, if possible, corrected. Confirmatory tests of circulation or EEG may be necessary.

B. Hypothermia.—Criteria for reliable recognition of death are not available in the presence of hypothermia (below 32.2 °C core temperature). The variables of cerebral circulation in hypothermic patients are not sufficiently well studied to know whether tests of absent or diminished circulation are confirmatory. Hypothermia can mimic brain death by ordinary clinical criteria and can protect against neurological damage due to hypoxia. Further complications arise since hypothermia also usually precedes and follows death. If these complicating factors make it unclear whether an individual is alive, the only available measure to resolve the issue is to restore normothermia. Hypothermia is not a common cause of difficulty in the determination of death.

C. Children.—The brains of infants and young children have increased resistance to damage and may recover substantial functions even after exhibiting unresponsiveness on neurological examination for longer periods compared with adults. Physicians should be particularly cautious in applying neurological criteria to determine death in children younger than 5 years.

D. Shock.—Physicians should also be particularly cautious in applying neurological criteria to determine death in patients in shock because the reduction in cerebral circulation can render clinical examination and laboratory tests unreliable.

editorials

Epidermolysis Bullosa Research Association

Voluntary health associations have made enormous contributions to the control of many major diseases. The National Tuberculosis Association (NTA), established in 1903, was one of the first to be organized, and others that followed patterned their organizational structure and activities after the NTA. The major strength of voluntary health groups is the cooperative effort and understanding they create between physicians and lay persons who together share responsibilities on governing boards and committees.

The main activities of voluntary health associations are support of research, public education service to patients, support of professional education, and advice to government on legislation and regulation. The control of tuberculosis and the conquest of poliomyelitis, advances in the prevention and treatment of heart disease, and the success of renal dialysis and transplantation are examples of what can be accomplished by voluntary health agencies. These successes have served to encourage the formation of other groups whose members have a special concern for a disease that has afflicted a family member or friend. Most of the voluntary health groups organized in recent years have been small in size and have directed their attention to relatively uncommon diseases. These organizations face an uphill battle for recognition, are unable to raise large sums of money to support their activities, and often are battling against diseases that will not yield to current research technology. Often, however, the greater the challenge, the greater the enthusiasm of those who are being challenged.

A recent addition to the voluntary health movement is the Epidermolysis Bullosa Research Association. Although the prevalence of epidermolysis bullosa in the United States is not precisely known, the new association has identified more than 1,500 cases and believes that through increased research this distressing disorder may either be prevented or more definitively treated. Epidermolysis bullosa is a group of inherited skin disorders, characterized by the formation of blisters that follow mild trauma. The genetic basis for these disorders make them a lifelong problem for those unfortunate enough to inherit the disorder. Like other chronic diseases, it arouses greater concern and interest in the establishment of a society than do acute self-limited diseases.

The Epidermolysis Bullosa Research Association is interested in receiving reports of research on epidermolysis bullosa, in recruiting both lay and medical professionals to its ranks, and, of course, in receiving donations to advance its cause. Interested persons should contact the executive director of the association at 2936 Avenue W, Brooklyn, NY 11229.

William R. Barclay, MD

Guidelines for the Determination of Death

The report on "Guidelines for the Determination of Death" in this issue (p 2184) is a landmark document with far-reaching medical, ethical, and legal implications. It is a summary of currently accepted medical practices for the determination of death, both cardiorespiratory and neurological, although the majority of the report is devoted to the diagnosis of neurological, or brain, death. Physicians from numerous specialities contributed to the drafting of this report, which was coordinated by the staff of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. These guidelines are included as an appendix to the more comprehensive report by the President's Commission on "Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death" (this entire report was approved by the President's Commission and sent to the President on July 9, 1981).

Until now, the most widely accepted standards for brain death in the United States have been the criteria developed by the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, published in *JAMA* in 1968 (205:337-340). These new guidelines are an update of currently accepted standards in the light of a great body of clinical experience accumulated since the original report of the Harvard Committee, and the development and refinement of new technologies in the laboratory confirmation of the diagnosis.

This report is important primarily because so many physicians were able to reach a consensus on a common set of guidelines, even though there were (and still are) differences of opinion on specific aspects of the criteria, and the signatories were aware of the ethical and legal implications of developing a set of national standards. For this many physicians from the fields of neurology, neurosurgery, electroencephalography, critical care medicine, anesthesiology, and legal medicine to reach a consensus is truly a remarkable achievement, of which the medical profession can be proud. Efforts such as this suggest that physicians have recognized the need for cooperation in developing standards in areas of controversy. In the next few decades, it will become more apparent to the medical community that it will need to take positions on even more controversial issues. Future statements will cover such areas as organ donation, "do not resuscitate" orders, and guidelines for the termination of treatment of "hopelessly ill" patients.

This report is not the final word on standards for determining death, but it is an important step forward in society's attempts to deal with bioethical dilemmas brought about by advances in medical technology, and it further reinforces the view that the medical profession must and will continue to assume a leadership role in these endeavors.

William R. Barclay, MD

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ATTACHMENT D

Excerpts from

Catastrophic Diseases: Who Decides What?

A Psychosocial and Legal Analysis
of the Problems Posed by Hemodialysis
and Organ Transplantation

Jay Katz and Alexander Morgan Capron

Russell Sage Foundation New York

1975

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4. Selection of Donors

One resource for the modern treatment of the catastrophic illnesses discussed here is unique: organs for transplantation. Since this resource is so unusual, we have chosen to treat it separately from the discussion of those resources (including artificial organs) whose supply is largely dependent on economic factors. We begin with a discussion of formulating policy on how to obtain organs (which is brief in light of the similarity of the issues to the questions discussed concerning the distribution of resources); this is followed by sections in which donations from living and dead persons are discussed.

a. Policies on Obtaining Organs. As is true for other resources, the central fact about transplantable organs is their scarcity. Consequently, well thought-out policies are required to increase the supply. The least expensive and most readily available sources consists of cadaver organs, primarily from accident victims.[88]

Prior to 1968, organ donation in this country was complicated by anachronistic legal provisions designed to prohibit graverobbing and by the absence of clear rules specifying the interests which could exist in a dead body and who could exercise them. The promulgation of the Uniform Anatomical Gift Act (UAGA) in the summer of 1968, and its subsequent adoption by all states and the District of Columbia, went a long way to cut through the fog which had enshrouded the subject. Under the Act, a person has the right during his lifetime to permit or forbid the use of his organs for purposes of treatment, research, and teaching after his death; if he fails to act, the organs can be donated by his next-of-kin (according to an order of priority established by the Act) after the person has died. The donee can be an individual patient or a physician or hospital, with the latter being free to use the organs as needed locally or elsewhere.[89]

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[88] *See, e.g.*, Dukeminier, *Supplying Organs for Transplantation*, 68 MICH. L. REV. 811, 814-15 (1970)—citing statistics that 10,000 kidney transplants could be performed per year in this country if immunological problems are solved, and that there are approximately 10,600 suitable cadaver kidneys available each year.

[89] Thus, the organ-typing and patient-matching program operated for kidneys by Dr. Paul Terasaki's group at U.C.L.A. provides for hospitals to share the kidneys available to them on a nationwide basis, for which they receive "credits" that put them higher on the list for a cadaver organ the next time a "compatible" one is available. *See* Terasaki, Wilkinson & McClelland, *National Transplant Communica-*

In effect, the UAGA creates a "market" system with a zero price for organs (although the donee, by custom or contract, sometimes pays the cost of the donor's final hospitalization as well as the expense of removing the organ). The system relies on individual choice, with a leading role being taken by physicians who in most circumstances are the initiators of the donation. While no reliable figures are yet available to establish the impact the UAGA has had on the level of donation, it is generally agreed that not enough organs are being donated to meet present need, and some commentators doubt that the current method will ever produce sufficient donations.[90]

In its place a number of alternatives are possible. The first would simply add a payment procedure to UAGA-type organ transfers. Although the Act speaks of "donations," its terms do not prohibit sales as well. It is uncertain, however, that individuals would express much interest in an offer to sell a right to one's organs after death (with present payments), since the purchaser would have little assurance that the seller would die at a time and place or in a manner conducive to useful organ donation.[91] It would be possible, however, to make payment to a terminally ill patient, or, after his death, to his estate. Sales of this type might, however, pose serious psychological threats for dying patients and impose unwanted pressures on the next-of-kin.

The sale of "spare" organs by living donors for immediate delivery raises fewer logistical and psychological problems. Jesse Dukeminier, Jr., found "no statute in an American state expressly prohibiting the sale of a spare organ"[92] but nevertheless suggested that making a payment to a live donor raises the prospect of civil and criminal liability for the physician removing the organ. While we do not share his concern on these points, we doubt that payment is wise for policy reasons. As Richard M. Titmuss has argued with considerable force, a major fault with the American system of collecting blood is that the existence of paid donors discourages volunteers.[93] While all the data necessary to support his argument are not available, the

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tions Network, 218 J.A.M.A. 1674 (1971). This type of arrangement is discussed in greater detail in Chapter Nine.

[90] *See, e.g.*, Sanders & Dukeminier, note 53 *supra*, at 394 *ff.*; Note, *Compulsory Removal of Cadaver Organs*, 69 Colum. L. Rev. 693 (1969) [hereinafter cited as *Compulsory Removal*].

[91] If the purchaser is the state (or other national organization) the problem of location is reduced somewhat. Were *A* to buy the right to *B*'s organs at the time of the latter's demise, *A* would not want *B* to die in a distant city where his organs would do *A* no good. Were the government to purchase the organs, it might be less concerned, since they could probably be put to use in any of a number of locations.

[92] Dukeminier, note 88 *supra*, at 850.

[93] R. Titmuss, The Gift Relationship: From Human Blood to Social Policy (1971).

danger that payment for organs (kidneys in particular) would decrease "altruism" among donors and their next-of-kin is one reason for not permitting payment for organs.[94] Furthermore, since the poor would probably sell organs disproportionately, this system would probably be subject to a charge of "exploitation."

An alternative which is likely to increase the supply would be to presume that organs may be removed from any corpse unless a prior objection has been raised. In the proposal made by Dukeminier and Sanders,[95] objection could be raised "either by the decedent during his life or by his next-of-kin after the decedent's death."[96] Giving a role to the relatives is intended to permit them to protect their religious beliefs and is also a recognition that most transplanters would hesitate to go ahead if relatives were to claim that the deceased objected to the removal of his organs—even if they could produce no "proof" of this fact within the short time in which organs remain "viable" after a person's death. Yet as others have noted, by requiring the transplanters to make sure that the relatives do not object, the Dukeminier-Sanders plan places as much of a burden (in terms of effort to secure consent and danger of delay) on the system as the existing procedure.[97] The debate thus turns on whether society would find a system of choosing to give ("opting-in") or choosing not to give ("opting-out") more acceptable.

If the right to object were to be left solely with the person whose organs are to be removed, the process of obtaining organs could be greatly simplified and the number of available organs would doubtless increase greatly. The presumption in favor of routine salvaging would have to be widely publicized and "opting-out" made as simple as sending a preaddressed postcard to a central computer registry which could be consulted by a surgeon prior to organ removal.[98] Before the enactment of the UAGA, questions might have arisen whether such an arrangement would give sufficient attention to the next-of-kin's rights over the corpse. The UAGA made clear, however, that these rights, if they ever existed, are subject to alteration or abolition by the legislature; the decedent's determination to give his organs for transplantation or other use is binding, despite any objection on the part of his relatives. It seems equally valid to reduce relatives' control so as to permit removal of the organs unless a deceased had objected. A more difficult question is raised if the relatives claim an objection on religious grounds. On the one hand, the deceased was in a position to forbid use of *his* body if he shared his relatives' view. On the other hand, the relatives may claim that their religion does not make requirements about the burial of one's *own* body but about those of one's kin. This argument may prove too much, however. On this logic, could not the relatives equally well claim a "right" to control *any* body, whether the deceased be a relative or a member of their church or not?[99]

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[94] If the government purchases the organs, would it do so in every case (at a high cost in resources thus diverted from lifesaving therapy)? If not, on what basis would it decide when to pay and when not? (If on the basis of wealth of the corpse, why not employ more direct means of income redistribution?) If individuals were to buy the organs, it would amount to the creation of a market system on the distribution side, with all the problems discussed earlier in subsection 3(c)[i].

[95] *See* Sanders & Dukeminier, note 53 *supra*, at 410-13; Dukeminier, note 88 *supra*, at 837-42; Dukeminier & Sanders, *Organ Transplantation: A Proposal for Routine Salvaging of Cadaver Organs*, 279 NEW ENG. J. MED. 413 (1968).

[96] Dukeminier, note 88 *supra*, at 837.

[97] Sadler, Sadler, Stason & Stickel: *Transplantation: A Case for Consent*, 280 NEW ENG. J. MED. 862 (1969).

[98] A central renal registry was part of a plan, along the lines outlined here, proposed by the Advisory Group on Transplantation Problems appointed by the Health Ministers in Great Britain and chaired by Sir Hector MacLennan, M.D. *See Advice*

A more far-reaching restriction on the right to object could abolish this right altogether, making donation compulsory,[100] as autopsies already are under certain conditions.[101]

> Moreover, if organs are treated as property of the decedent, the decedent may have no power to order destruction of his organs by burial or cremation so long as the organs have value. It has been held in a number of cases that a direction to destroy one's own property at death is against public policy and is therefore void.[102]

While these and other analogies suggest that the public interest in saving lives through transplantation is great enough to justify making organ removal automatic (when medically useful), the policy issues (such as impact of this method on the emotions and personal feelings of the survivors) need to be openly debated before legislatures take such a step. Furthermore, since the donor is also deprived of the right to object, the religious considerations mentioned previously would loom much larger. If it is possible for the government to "accommodate its purpose [*i.e.*, saving lives] by

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on the Question of Amending the Human Tissue Act 1961 (Cmnd. 4106) National Health Service (1969). Their recommendations were embodied in a Renal Transplant Bill, which was not adopted.

[99] If the deceased had been a member of their church, he could have chosen to "opt-out" of donation himself.

[100] *See Compulsory Removal*, note 90 *supra*.

[101] *See, e.g.*, Young v. College of Physicians & Surgeons, 81 Md. 358, 32 A. 177 (1895); Sturgeon v. Crosby Mortuary, Inc., 140 Neb. 82, 299 N.W. 378 (1941).

[102] Dukeminier, note 88 *supra*, 834.

means which do not impose such a burden,"[103] then compulsory removal of cadaver organs would run afoul of the First Amendment.

The only way to establish the need for a compulsory system, in other words, is to try less restrictive systems and see if they will produce an adequate supply. We believe that, for the moment, present policy, as embodied in the Uniform Anatomical Gift Act, ought to be given a fair trial first. Studies should, however, be conducted to determine whether the Act is adequately facilitating donations and whether any of its features should be revised. The real need for a change in policy on the obtaining of organs will arise when and if transplantation technology overcomes the problem of rejection and establishes itself as a highly successful form of therapy. If, under these circumstances, it appears that a change in procedure is warranted, prime consideration should be given to the "opting-out" system proposed by the MacLennan committee in Great Britain.[104] While it might be objected that in the case of a patient who had *not* opted-out, the attending physician would feel unwarranted pressure to forego necessary treatment so as to speed death, it seems likely that the very much greater supply of organs that could be expected under such a system would on the whole *reduce* the pressure in each individual case.

b. Donation by Living Individuals. Thus far the policies under discussion have been ones which require a societal judgment, and we have spoken in terms of legislative action. As we turn now to issues that have been dealt with largely through the private ordering of physicians, hospitals, patients, donors, and their families, the question arises whether a need exists for more broadly representative groups to engage in formulating policy more openly and explicitly. The following discussion will treat separately the donation of paired and unpaired organs, with primary attention devoted to the formulation of policies concerning the former.

i. PAIRED ORGANS. As described in Chapter Four, living donors have been an important source of kidneys for transplantation since the earliest days of the procedure. Patients' relatives were the donors in more than 30 percent of all kidney grafts to date and they continue to provide an important source of organs. Unrelated living donors, by contrast, gave 14.5 percent of the kidneys in the 14 years prior to 1967 for which records are available, but have not been used as donors at all since 1969.[105] Since the failure to employ this source does not stem from any ready availability of organs from other sources (as has already been noted), it must be a result of transplant surgeons' choice—and, in fact, this situation provides a valuable illustration of policymaking by physicians.

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[103] Braunfield v. Brown, 366 U.S. 599, 607 (1961).

[104] *See* note 98 *supra.*

[105] *See* Advisory Committee to the Renal Transplant Registry, *Ninth Report of the Human Renal Transplant Registry,* 220 J.A.M.A. 253 (1972). In addition to the 122 organs included in this figure for 1953-1966, and 144 to date, there have been to date 31 donations by spouses, who are also "unrelated" in the genetic sense. On the other hand, Dr. Carl Fellner concludes on the basis of the early reports (which contained a finer breakdown of donor categories) that more than half of the kidneys

The reasons physicians have difficulties in using unrelated donors are not hard to fathom. Outside of research settings, physicians are not used to dealing with persons who will derive no therapeutic benefit from an intervention. Although some transplanters made use of live, unrelated donors in the early days of renal grafting, perhaps because less was known about how to keep cadaver organs viable and because the experimental nature of the procedure meant that all (recipients as well as donors) were taking risks, gradually there emerged a "distrust and suspicion toward the motivation of such [unrelated live] donors and a definite repugnance concerning their use."[106] Dr. Harrison Sadler and his colleagues discovered from a careful study of 18 unrelated donors that the primary motive for their donation was not "the satisfaction of drives or the discharge of infantile impulses, but the very personal area of self-identity, a self-ideal quite unconscious to them at the time."[107] In spite of their published findings, the Sadler group "continued to hear the remark, 'they [unrelated donors] must be crazy to do such a thing, no matter what you say—they are perverted'."[108]

This kind of thinking on the part of transplanters has rarely been expressed in formal rules or statements.[109] Although no live related renal donors have been used for three years in the United States, the policy of physicians as publicly stated does not bar such employment and the International Transplantation Society even acknowledges "that the wish to donate an organ need not be a sign of mental instability."[110] The deviation of

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from unrelated donors were "free kidneys" obtained from persons who had to undergo a nephrectomy for reasons unrelated to transplantation. Fellner, *Altruism Revisited: The Genetically Unrelated Living Kidney Donor* (consultant's memorandum), at 4 (1972) [Appendix E].

[106] Sadler, Davison, Carroll, & Kountz, *The Living Genetically Unrelated Kidney Donor*, 3 SEMINARS IN PSYCH. 86 (1971). *See also* pp. 93-94 *supra*.

[107] Sadler, *Summary Notes on a Clinical Decision-Making Model* (consultant's memorandum), at 1 (1972) [Appendix H].

[108] *Id.*

[109] The French position, as expressed before the National Academy of Medicine in October 1970 by Dr. J. Dormont, is that "the donor must . . . be chosen exclusively from among the close relatives of the recipient." Dormont, *Les Problèmes Moraux de la Transplantation d'Organs*, 154 BULL. ACAD. NAT. MED. (PARIS) 623 (1970).

[110] Hamburger, et al., *A Declaration of the International Society of Transplantation*, 12 TRANSPLANT. 77 (1971). *Cf. Bar Council Report on Organ Transplants*, 3 BRIT. MED. J. 716 (1971)—approving organ removal from a mentally competent donor over 16 years of age who has given his written consent after he had been fully advised of the risks.

practice (or one could say, tacit medical policy) from official policy is, at the moment, not too distressing because the success rate of kidney grafts from unrelated donors is still below that of any other category (including cadavers), since present tissue typing methods apparently do not permit the identification of certain important antigenic factors which are absent (although undetected) in related donors such as siblings. But, as Dr. Fellner notes,

> it is only a question of time before tissue matching with the help of HL-A antigen typing, and other typing systems yet to be found, will have progressed to the point where, for organ transplantation purposes, the equivalent of a monozygotic twin could easily be pinpointed in the population at large.[111]

Before such time arises, it will be necessary for policy to be formulated on this subject making clear whether genetically unrelated donors should be accepted. This is a question which cannot be resolved by physicians alone. It concerns such issues as: (1) Does society have any interests in preventing a person from making a gift (or, as discussed previously, a sale) of an organ if that creates risk to his own life? (2) What level of risk is acceptable? (3) What level of "success" of the transplant is necessary, if any, to justify the donor's risk? (4) How does the availability of organs from other sources, such as cadavers or living *related* donors, affect the decision? (5) What is the relevance of different success rates between living unrelated donors and other sources? And (6) what is the relevance of surgeons' beliefs with respect to the use of organs from unrelated donors?

While these questions must be addressed by a public policymaking body, such as a special advisory group to the National Institutes of Health or to legislatures, it is our opinion that evidence already exists to indicate that there are reasons of policy, if not of medicine, to prefer unrelated rather than related donors. Unlike Sadler's findings about unrelated donors (who were accepted only if they persisted on their own initiative in their offer, over a number of months and without encouragement from the transplant center), there are many indications that related donors were not true volunteers, participating of their own free will. One study showed that such donors did not reach their decisions in the thoughtful, rational manner which had been assumed by the theorists on consent.[112] Moreover, despite physicians' attempts to protect the donor from undue pressures, it is apparent that veiled or even open pressure from family members as well as unconscious feelings of obligation and other psychological factors weigh heavily on family donors.[113]

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[111] Fellner, *Altruism Revisited*, at 1 (1972) [Appendix E].

[112] Fellner & Marshall, *Kidney Donors: The Myth of Informed Consent*, 126 AM. J. PSYCHIATRY 1245 (1970); *see also* Fellner & Marshall, *Twelve Kidney Donors*, 206 J.A.M.A. 2703 (1968); notes 27-36 & accompanying text *supra*.

> In most instances, no real decision-making problem existed for the donor. Most commonly, he stated that he must give to save the life of the potential recipient or he could not face himself. In a sense, he is "called." It is not always a call about which he is enthusiastic, but it is one which he believes he is unable to refuse.[114]

From such observations by others and from a review of his own interviews with donors (who typically declared "I had to do it"), Dr. Fellner argues that "most donors do not act out of pity or altruism but out of a feeling that they have to do this for their own sake."[115]

If this analysis is correct, then physicians appear to have adopted an informal policy which excludes people as donors whom the physicians believe act from "improper" motives and must be "crazy," when in fact those people's donations are a far more "voluntary" expression of their own choice and a more "genuine" reflection of a well integrated person than are the donations made by family donors. There is thus a need for others, who themselves are not so emotionally involved as the transplanters clearly are, to participate in the formulation of policy in this area.

Some additional light on decisionmaking with respect to live donors is thrown by contrasting medical policy on unrelated donors with that on the use of related donors who are incapable of giving valid consent. In most circumstances, no thought would be given to using such donors; however, where a child in renal failure has an identical twin, physicians favor use of the twin as an organ donor since the prognosis is so favorable.[116] Since minors[117] cannot themselves consent to operations, and since it is believed that parents or guardians cannot give permission when the procedure is not intended to benefit the child,[118] refuge has been taken in court actions. In these cases, the judiciary has uniformly approved the physicians' and parents' request for permission to transplant a kidney from the well to the ailing twin. In the first cases,[119] the children were teenagers, who one may assume were old enough at least partially to comprehend the contemplated operation; thus, their consent and agreement to having their kidneys removed properly played a role in the courts' reasoning. More recent cases have involved much younger children.[120] Here, the weight of the decisions has been cast onto the argument that the child-donor *does* receive a benefit by avoiding the psychic harm which would arise from the loss of the twin. This seems to be an attempt on the part of the judiciary to avoid having to confront the policy question of using nonconsenting individuals as donors. Some commentators, such as David Daube, have been sharply critical of the present practice.[121] There is a pressing need to engage in an open policy debate on this subject, which will touch many of the same questions of comparative benefits and risks set forth previously in the discussion of unrelated donors and which will also raise the whole issue of the use of children in medical research. This debate should eventually lead to proposals by professional and legislative bodies alike as to the policies which are to guide these research activities.

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[113] *See, e.g.*, Simmons, Hickey, Kjellstrand, & Simmons, *Family Tension in the Search for a Kidney Donor*, 215 J.A.M.A. 909 (1971); Crammond, *Renal Homotransplantation: Some Observations on Recipients and Donors*, 133 Brit. J. Psych. 1223 (1967).

[114] Eisendrath, Guttman & Murray, *Psychological Considerations in the Selection of Kidney Transplant Donors*, 129 Surg. Gynec. & Obstet. 243 (1969).

[115] Fellner, *Altruism Revisited*, at 8 (1972) [Appendix E]. He also believes that these donors experience a feeling of power from their act and gain in self-esteem.

[116] Since 1967, one- and two-year survival rate for monozygotic twin transplants has been 100 percent. *Ninth Registry Report*, note 105 *supra*, at 256. Dialysis is not favored as a method of treating children with kidney disease because of the adverse effects of the treatment and dietary regime on growth and possibly on the child's psyche.

[117] Customarily defined as persons under 21, although most states have now made 18 the age of majority.

ii. UNPAIRED ORGANS. The donation of an unpaired organ is tantamount to taking one's life. For this reason, we know of no situation in which such a donation has been permitted. Paul Blachly has suggested, however, that persons engaged in "suicide-prevention" discuss with those intent on suicide that they donate a paired organ instead.[122] Blachly argues that since potential suicides usually involve depression and feelings of unworthiness, the opportunity to help others in a dignified fashion may be very therapeutic. Similarly, the attention given a donor has been viewed as very valuable in overcoming the inner forces leading a person to contemplate taking his own life. When it comes to the "inevitable case" that still insists upon suicide, the question arises whether we should overcome our present mores

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[118] Although, as was discussed in Chapter Six, the kidney cases in minors are usually taken to exemplify the problem of obtaining valid permission for a nonbeneficial intervention, they involve an additional element: namely, that the parents face a conflict-of-interest in desiring to help the ailing child through a donation by the well child. This conflict may becloud the parents' judgment more than would be true in other nonbeneficial (research) interventions.

[119] The earliest cases are three unreported Massachusetts decisions growing out of operations performed at the Peter Bent Brigham Hospital. The cases are discussed in Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U.L. REV. 891 (1959).

[120] Hart v. Brown, 289 A.2d 386 (Conn. Super. Ct. 1972)—approval of transplant in seven-year-old twin girls. In Strunk v. Strunk, 445 S.W. 2d 145 (Ky. 1969), the donor was a 27-year-old inmate of a state mental institution; he was found to have a "mental age of approximately six years."

[121] "Children should on no account be donors, and there should be no cheating by maintaining . . . that the child would suffer a trauma if he were not allowed to give his twin a kidney or whatever it might be." Daube, *Transplantation: Acceptability of Procedures and the Required Legal Sanctions*, in ETHICS IN MEDICAL PROGRESS: WITH SPECIAL REFERENCE TO TRANSPLANTATION 188, 198 (G.E.W. Wolstenholme & M. O'Connor eds. 1966) [hereinafter cited as MEDICAL PROGRESS].

> to permit such a person to end his own life in a dignified way which would permit utilization of his organs. . . . One would think that the stigma that the friends and relatives attach to a suicide would be much lessened if they knew several persons would live as a result.[123]

The issue of "positive euthanasia" which is raised in an oblique fashion by this suggestion was confronted directly a number of years ago by one of our consultants, Dr. Belding H. Scribner, in his presidential address to the American Society of Artificial Internal Organs:

> [I]f I knew that I had a fatal disease I would seriously consider volunteering to donate one of my kidneys while I was still well. As far as death is concerned, I would like to be able to put into my will a paragraph urging that when my physician felt that the end was near, I be put to sleep and any useful organs taken prior to death. . . . I think that ethical and legal guidelines should be devised to permit me and others to volunteer in these ways.[124]

At the present time a number of groups and individuals are drafting statutes on euthanasia and urging their enactment.[125] Although we doubt that such measures would meet with widespread approval today, and we have not seen any which avoid the conflict-of-interest problem without an impossibly cumbersome judicial mechanism, we think it is appropriate for persons working in the catastrophic disease area to show the effect which euthanasia could have on the treatment of disease.

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[122] Blachly, *Can Organ Transplantation Provide an Altruistic-Expiatory Alternative to Suicide?*, 1 LIFE-THREATENING BEHAVIOR 6 (1971).

[123] *Id.* at 9. We would reject this specific proposal because it can easily lead to exploitation of the therapeutic relationship.

[124] Scribner, *Ethical Problems of Using Artificial Organs to Sustain Human Life*, 10 TRANS. AM. SOC. ART. ORGANS 209, 211 (1964).

[125] The primary concern of the euthanasia proponents is not, of course, organ transplants but the pain and expense involved in the prolonged care of terminal, debilitated and often unconscious patients.

ATTACHMENT E

Excerpts from

Catastrophic Diseases: Who Decides What?

A Psychosocial and Legal Analysis
of the Problems Posed by Hemodialysis
and Organ Transplantation

Jay Katz and Alexander Morgan Capron

Russell Sage Foundation *New York*

1975

Present organ-sharing arrangements are informal and nonbinding. "Once the kidneys are obtained, how they are distributed is currently a matter mostly of who salvaged the kidneys."[22] Although it is true under the Uniform Anatomical Gift Act that physicians act as "recipients" of cadaver organs, it is clear that the intent of the Act was that they were only trustees and that they need be given no personal control over who receives the organs. Therefore, there should be no legal impediments to moving beyond the present informal systems, such as that operated out of UCLA. More than 500 organs have already been shared among more than 90 transplant centers through the UCLA tissue-matching and recipient registry, but the nonmandatory nature of the system creates problems of its own. Less than the best matches occur for two reasons. First, participating transplant centers typically share only one kidney from the cadaver and keep the other for one of "their own" patients. Second, a center which has shared a kidney gets a "credit" which places it in a preferential position for receiving future kidneys from other centers.

The emphasis on the "ownership" of the donated kidney thus biases the choice of the recipients according to the center at which they are awaiting treatment rather than solely according to the medical probabilities (*e.g.*, closeness of tissue type, surgical success record of physician performing the operation, etc.). As techniques of organ preservation and tissue matching are perfected, there is no excuse for a continuation of a system which relies on arbitrary, nonmedical factors in the assignment of scarce resources such as cadaver organs.[23] If a transplant center wishes to participate in a national organ-sharing arrangement, in order to increase the range of tissue types it can offer to patients, it should be obliged to share all the cadaver organs which become available to it. We are not persuaded of the danger that physicians' motivation to seek cadaver organs will be destroyed if the organs are going to be shared with the best-matched patients at other hospitals. The greater supply of, and better chances with, such organs will provide sufficient motivation for physicians, who—like potential donors and their families—will be made more aware of organ donation as a contribution to an important national need with the potential of saving many lives.

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[22] Terasaki, *Organ Transplantation* (consultant's memorandum), at 3 (1972) [Appendix K]. The informal system of organ sharing has nevertheless been remarkably successful, although a much greater degree of organization and cooperation would be needed to produce an adequate supply of cadaver kidneys. By 1972 nearly half of all cadaver kidneys transplanted were obtained from other hospitals (600 shared within the same city and 455 shared between cities). A wide, national pool of donors and recipients is particularly necessary to avoid mismatches caused by lymphocytotoxins. *See* Opelz & Terasaki, *National Utilization of Cadaver Kidneys for Transplantation*, 228 J.A.M.A. 1260 (1974).

[23] *See* Terasaki, Wilkinson & McClelland, *National Transplant Communications Network*, 218 J.A.M.A. 1674-78 (1971).

2. Research v. Therapy

An example of a national administrative decision of a very different type would be the need to decide when an intervention designated as "research," in the sense discussed in Chapter Eight, has become "therapeutic." Although basic policies on this and similar matters will have been established previously at the formulation stage, these policies are not self-executing. Thus, national bodies must keep abreast of the progress of catastrophic disease research and treatment in order to determine, *inter alia,* when a procedure which had been available only on a limited "research" basis should be more widely offered or whether a procedure which had called for review by the local Institutional Advisory Committees should be regarded as no longer needing protocol approval.

ATTACHMENT F

Excerpts from

Summing Up

Final Report on Studies
of the Ethical and Legal
Problems in Medicine
and Biomedical and
Behavioral Research

March 1983

President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research

* * *

Limited Resources. As has already been noted, the principles of serving well-being and promoting self-determination sometimes point in conflicting directions. Yet in the normal course of treatment and research, pursuing them in tandem tends toward the achievement of people's health as they define it. The capabilities of the biomedical sciences both to prevent and to cure illness have expanded immensely in the past half-century; today, health care can offer dramatic remedies for previously untreatable conditions. Nonetheless, an important factor confounds the pursuit of the goal of good health to the full extent indicated by the well-being and self-determination principles: the inescapable reality of limited resources. As the capabilities of health care have expanded, the strain placed on already strapped personal budgets, employer-provided health benefit programs, and the treasuries of governments at all levels—from local to Federal—has become a matter of increasing concern.

The reality of restricted resources means patients, health care professionals and institutions, and society at large must face an ethical problem: having to choose the uses to which limited—in some cases, very scarce—resources will be put. The choices require comparing health care expenditures with other areas of public and private spending, as well as with choices within the health care budget—between treatment and research; between restorative steps for those already ill and preventive steps for those who may be at risk; among different age-groups, diseases, treatment settings, and so forth.

The ethical dilemmas created by the competition for limited resources were vividly displayed in the late 1960s by the efforts to save the lives of patients with kidney failure. Two treatments were available. First, if a donor could be found, a patient's diseased kidneys could be replaced by a healthy kidney. Transplantation offered a "cure" when it was successful, but the supply of kidneys was inadequate and even when transplantation occurred in most cases it did not succeed because of organ rejection, infection, or the failure of the new kidney for some other reason. Alternatively, patients could undergo hemodialysis two or three times a week, during which their blood was run through a machine for six to eight hours to cleanse it of impurities. While improvements were constantly being sought in both forms of treatment, dialysis was regarded as a proven and reliable (albeit arduous and expensive) method for saving the lives of people who were often otherwise healthy and who, if treated, could look forward to an indefinite continuation of a nearly "normal" life.

Since there were many more people with end-stage renal disease than the dialysis facilities could accommodate, various methods were adopted to select the patients who would be treated. The tragedy of the situation received extensive coverage in the media, including articles about groups like the "God Committee" in Seattle, ordinary citizens who had to decide who in their community most deserved this life-saving resource. At other hospitals, dialysis was allocated on a first-come-first-served basis or according to patients' ability to pay.[9]

By the early 1970s—as the number of people treated moved beyond the small percentage it had been during the early, experimental stages to a greater (though still fractional) portion of the total need—the contrasting fates of those treated and the larger number who died untreated—became intolerable. Rather than continue to seek methods of allocating the resource fairly, a decision was made to make it available to every American with end-stage renal disease under a special provision in the Medicare program.

This response to the dilemma of limited resources is understandable. Indeed, it may have been inevitable, given the drama of identifiable patients who died because they could not obtain life-saving medical treatment. Moreover, the cost of overcoming the tragedy seemed acceptable—in part because of the way in which the number of "eligible" patients was estimated. Over the past decade, however, expenditures on the End Stage Renal Dialysis Program (now totaling approximately $2 billion per year) have exceeded the original estimates manyfold and the standards for eligibility for dialysis, no longer constrained by a scarcity of resources, have expanded to include many patients whose age or concurrent diseases would have left them out of the calculations of the relevant "pool" of patients in 1972.[10]

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[9] Jay Katz and A. M. Capron, CATASTROPHIC DISEASES: WHO DECIDES WHAT?, Russell Sage Foundation, New York (1975) at 184-96.

[10] This serves as another reminder of the interaction of "facts" and "values"—in this case, the understandable (and probably unconscious) tendency of physicians to exclude from eligibility for dialysis those patients whose characteristics made their prognosis least

Dramatic, "big ticket" treatments like kidney dialysis and transplantation—or the implantation of an artificial heart at the University of Utah Medical Center in late 1982—are not yet the major strains on the health care budget, but they do crystallize the ethical issues posed by limitations on society's resources. The Commission concluded that these issues cannot be avoided by the sort of response—"give everyone all they need"—that was used for kidney failure. Instead, the Commission turned to the ethical principle of equity. This principle is always a hard one to know how to apply—as can be seen in the role it played in several Commission reports.

It received greatest attention in the report on the ethical and legal implications of differences in people's access to health care. On the one hand, the Commission concluded that the importance of health care—in promoting well-being, preventing death and disability, relieving pain, restoring functioning, and generally ensuring opportunity—and the uneven and largely undeserved incidence of illness generated an ethical obligation of society in this area that does not necessarily exist regarding other things. Yet the principle of equity does not create a "right" to health care equal to all the care that some people may obtain for themselves, nor even all that people may want or need, in the sense of its being of some benefit. Rather, equity requires that people have access to an adequate level of care and that the costs of care be fairly distributed. As is always the case in dealing with general principles, such as equity, many of the hardest questions—such as "what level of care is adequate?" and "what constitutes fair distribution?"—remain to be resolved in the context of particular decisions. Instead of searching for a definitive interpretation of the concepts, the Commission attempted to set forth terms of reference by which those who are responsible for formulating policy on health care could compare the ethical implications of alternative proposals.

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favorable. Unlike choices between patients based on such social factors as wealth, education, marital and parental status, and the like, the criteria of "medical suitability" were regarded as "objective." With sufficient resources, it proved possible to redefine "suitability" since the patients with less favorable prognoses were no longer competing with those who "deserved" the treatment more because their prognoses were better. Though few would argue with a decision to use scarce resources for those most likely to benefit from them, any decision based on people's deserts is plainly one that involves values, not merely objective facts.

ATTACHMENT G

Excerpts from

Securing Access to Health Care

A Report on the
Ethical Implications of
Differences in the
Availability of
Health Services

Volume One: Report

March 1983

President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research

* * *

Meeting the Societal Obligation

How Much Care is Enough? Before the concept of an adequate level of care can be used as a tool to evaluate patterns of access and efforts to improve equity, it must be fleshed out. Since there is no objective formula for doing this, reasonable people can disagree about whether particular patterns and policies meet the demands of adequacy. The Commission does not attempt to spell out in detail what adequate care should include. Rather it frames the terms in which those who discuss or critique health care issues can consider ethics as well as economics, medical science, and other dimensions.

Characteristics of adequacy. First, the Commission considers it clear that health care can only be judged adequate in relation to an individual's health condition. To begin with a list of techniques or procedures, for example, is not sensible: A CT scan for an accident victim with a serious head injury might be the best way to make a diagnosis essential for the appropriate treatment of that patient; a CT scan for a person with headaches might not be considered essential for adequate care. To focus only on the technique, therefore, rather than on the individual's health and the impact the procedure will have on that individual's welfare and opportunity, would lead to inappropriate policy.

Disagreement will arise about whether the care of some health conditions falls within the demands of adequacy. Most people will agree, however, that some conditions should not be included in the societal obligation to ensure access to adequate care. A relatively uncontroversial example would be changing the shape of a functioning, normal nose or retarding the normal effects of aging (through cosmetic surgery). By the same token, there are some conditions, such as pregnancy, for which care would be regarded as an important component of adequacy. In determining adequacy, it is important to consider how people's welfare, opportunities, and requirements for information and interpersonal caring are affected by their health condition.

Any assessment of adequacy must consider also the types, amounts, and quality of care necessary to respond to each health condition. It is important to emphasize that these questions are implicitly comparative: the standard of adequacy for a condition must reflect the fact that resources used for it will not be available to respond to other conditions. Consequently, the level of care deemed adequate should reflect a reasoned judgment not only about the impact of the condition on the welfare and opportunity of the individual but also about the efficacy and the cost of the care itself in relation to other conditions and the efficacy and cost of the care that is available for them. Since individual cases differ so much, the health care professional and patient must be flexible. Thus adequacy, even in relation to a particular health condition, generally refers to a range of options.

The relationship of costs and benefits. The level of care that is available will be determined by the level of resources devoted to producing it. Such allocation should reflect the benefits and costs of the care provided. It should be emphasized that these "benefits," as well as their "costs," should be interpreted broadly, and not restricted only to effects easily quantifiable in monetary terms. Personal benefits include improvements in individuals' functioning and in their quality of life, and the reassurance from worry and the provision of information that are a product of health care. Broader social benefits should be included as well, such as strengthening the sense of community and the belief that no one in serious need of health care will be left without it. Similarly, costs are not merely the funds spent for a treatment but include other less tangible and quantifiable adverse consequences, such as diverting funds away from other socially desirable endeavors including education, welfare, and other social services.

There is no objectively correct value that these various costs and benefits have or that can be discovered by the tools of cost/benefit analysis. Still, such an analysis, as a recent report of the Office of Technology Assessment noted, "can be very helpful to decisionmakers because the process of analysis gives structure to the problem, allows an open consideration of all relevant effects of a decision, and forces the explicit treatment of key assumptions."[27] But the valuation of the various effects of alternative treatments for different conditions rests on people's values and goals, about which individuals will reasonably disagree. In a democracy, the appropriate values to be assigned to the consequences of policies must ultimately be determined by people expressing their values through social and political processes as well as in the marketplace.

Approximating adequacy. The intention of the Commission is to provide a frame of reference for policymakers, not to resolve these complex questions. Nevertheless, it is possible to raise some of the specific issues that should be considered in determining what constitutes adequate care. It is important, for example, to gather accurate information about and compare the costs and effects, both favorable and unfavorable, of various treatment or management options. The options that better serve the goals that make health care of special importance should be assigned a higher value. As already noted, the assessment of costs must take two factors into account: the cost of a proposed option in relation to alternative forms of care that would achieve the same goal of enhancing the welfare and opportunities of the patient, and the cost of each proposed option in terms of foregone opportunities to apply the same resources to social goals other than that of ensuring equitable access.

Furthermore, a reasonable specification of adequate care must reflect an assessment of the relative importance of many different characteristics of a given form of care for a particular condition. Sometimes the problem is posed as: What *amounts* of care and what *quality* of care? Such a formulation reduces a complex problem to only two dimensions, implying that all care can readily be ranked as better or worse. Because two alternative forms of care may vary along a number of dimensions, there may be no consensus among reasonable and informed individuals about which form is of higher overall quality. It is worth bearing in mind that adequacy does not mean the highest possible level of quality or strictly equal quality any more than it requires equal amounts of care; of course, adequacy does require that everyone receive care that meets standards of sound medical practice.

Any combination of arrangements for achieving adequacy will presumably include some health care delivery settings that mainly serve certain groups, such as the poor or those covered by public programs. The fact that patients receive care in different settings or from different providers does not itself

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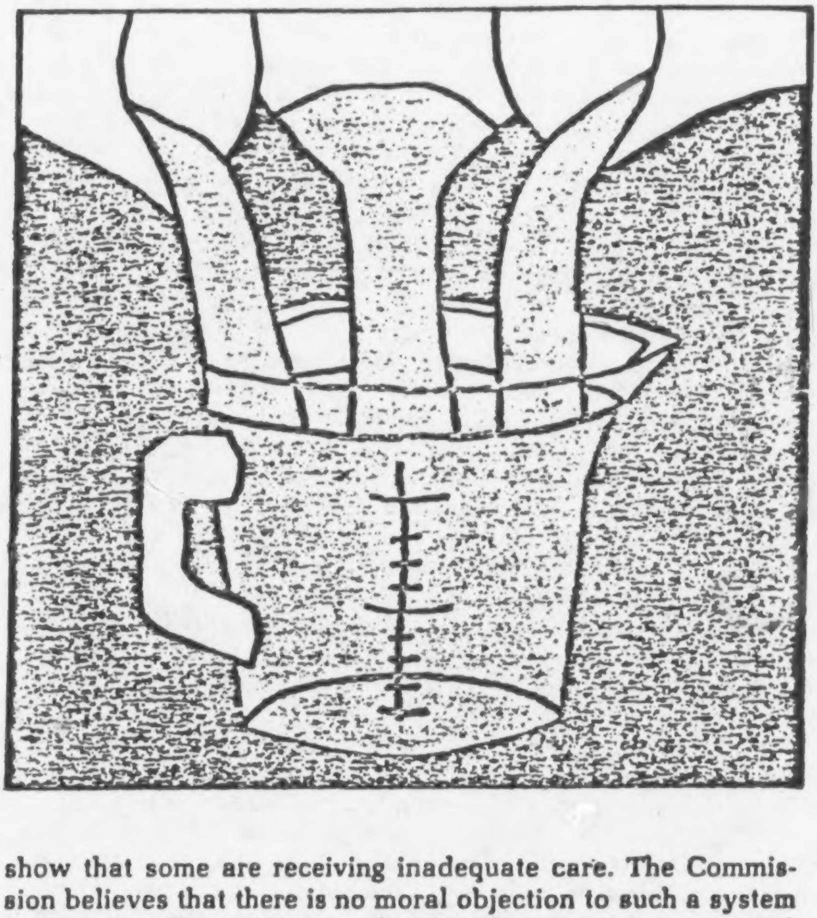
[27] Office of Technology Assessment, U.S. Congress, THE IMPLICATIONS OF COST-EFFECTIVENESS ANALYSIS OF MEDICAL TECHNOLOGY, SUMMARY, U.S. Government Printing Office, Washington (1980) at 8.



show that some are receiving inadequate care. The Commission believes that there is no moral objection to such a system so long as all receive care that is adequate in amount and quality and all patients are treated with concern and respect.

At this point, the complexity of the problem of deciding what constitutes adequate care is apparent. However, clear and useful conclusions can emerge even when there is no agreement on the details of adequacy. In the case of pregnant women, for example, there is a consensus in the United States that some prenatal care, the attention of a trained health professional during labor and delivery, and some continuity between the two are all essential for an adequate level of care.

A stronger consensus is required if proposals for change are to be evaluated. Some of the processes that may be used to develop a societal consensus on adequacy are already a familiar feature of the health care system, and do in fact play a role in determining the amount of care that is provided, especially to beneficiaries of public programs.[28]

Professional judgment. Physicians and other professionals who provide health care are familiar with human needs for care, so that the first means that might be employed in defining an adequate level of health care would be a reliance on individual health care practitioners' judgment of the "medical necessity" of any particular service. However, sole reliance on professional judgment in setting limits is not appropriate because of professionals' tendency to provide all possible medically beneficial care. At the very least, the extent and manner in which professionals exercise judgment to limit the use of care that is of little benefit (relative to cost) varies widely. Thus, without substantial changes in individual health care professionals' present practices, this method of defining adequate health care is likely to result in an uncertain and overly inclusive definition.

Another way that professional judgment might be used to define adequacy is to rely on the standards of medical practice as adopted by the professonal community through, for example, consensus conferences. The advantage of such an approach is the specialized knowledge of the effects of care that such people have. However, there are also serious disadvantages.

Professionals have no special expertise in deciding how the effects of medical care ought to be valued, either with respect to the relative value of different dimensions of care or, particularly, the value attached to health care relative to other goods. In the last two or three decades, for example, there have been major changes in prenatal and obstetrical care, in many cases in response to the preferences of parents: changes in the use of anesthesia; the kind of contact possible between mother, father, and infant in the hospital; the information provided to the family about the birth process; support for breast-feeding as opposed to formula-feeding. These changes were never shown to be harmful or uniformly beneficial, but rather represent differences in the valuing of benefits.[29]

Professionals often have no special knowledge of the costs of different alternatives and perhaps little appreciation of the other goods foregone for the sake of health care. Studies show that practitioners are frequently unaware of the financial costs of many of the tests and procedures that they order.[30]

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[28] For a discussion of determinations of the amount and type of care under public programs, see Chapter Three *infra*, although the processes now used would not necessarily have the same role in the determinations of adequacy recommended here.

[29] In many cases there is now a medical consensus that the new practices are in fact superior. Nevertheless, strong pressure from consumers was required to bring some of them about.

Finally, their involvement with the delivery of care may sometimes create a barrier to full consideration of all options. Many observers have noted a bias in health care in this country toward the introduction of expensive, high-technology-based procedures delivered by existing institutions and against the introduction of alternative ways to provide services at lower cost.[31]

Because of these factors, professional judgment cannot stand alone as the determinant of adequate care, but the specialized knowledge of health care professionals about the effects of health care is essential as part of any process of determining adequacy.

Average current use. The United States at present has a sophisticated health care system and there is reason to suppose that the average American obtains an adequate total amount of care. Defining adequacy in terms of the level of care presently enjoyed by the average person has the advantage of realism: it reflects the outcome of the health care system as it now operates—what actually happens as a result of patient-provider interaction, not merely what planners believe ought to happen.

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[30] "Indeed, there is ample evidence that medical students, interns, residents, and even medical faculty are equally uninformed about the prices of the tests and treatments they order." Anthony L. Komaroff, *The Doctor, the Hospital, and the Definition of Proper Medical Practice* (1981), Appendix U, in Volume Three of this Report, at *Education*, in section five. Komaroff cites a number of studies as examples: S.P. Kelly, *Physicians' Knowledge of Hospital Costs*, 6 J. FAM. PRAC. 171 (1978); S.J. Dresnick *et al.*, *The Physician's Role in the Cost-Containment Problem*, 241 J.A.M.A. 1606 (1979); J.K. Skipper *et al.*, *Medical Students' Unfamiliarity with the Cost of Diagnostic Tests*, 50 J. MED. EDUC. 683 (1975); L.R. Kirkland, *The Physician and Cost Containment*, 242 J.A.M.A. 1032 (1979).

[31] Dean David Mechanic of Rutgers University gives the following example of this:

> One of the most prevalent conditions among children is sore throats, and it is routine to take a throat culture before treatment to assess whether the cause is a streptococcal infection. Typically, the mother is required to bring the child to a pediatrician for the culture, often involving inconvenience and considerable expense. As an experiment at the Columbia Medical Plan has demonstrated, mothers can be effectively instructed to take a throat culture at home, negating the need for physician and nurse care in most instances and increasing the convenience and satisfaction of the mother. The barriers to individual responsibility *built in to* medical care must be reviewed carefully, and efforts should be made to modify them.

David Mechanic, FUTURE ISSUES IN HEALTH CARE: SOCIAL POLICY AND THE RATIONING OF MEDICAL SERVICES, The Free Press, New York (1979) at 37 (citation omitted).

Nevertheless, there are good reasons to pause before adopting "current use" as the benchmark of adequacy. Many distortions in people's true preferences for health care affect the average level of care received—for example, those whose access is now unduly limited bring down the average, while those who overspend for health care because of insurance and tax advantages (discussed in Chapter Three) inflate the average. Also, structural characteristics of the delivery system can mean that even people with good access do not necessarily receive an appropriate mix of services.

A possible variation of the concept of average use is to adopt as a point of reference the care received by people of average financial means who live in areas that are sufficiently provided with health care resources. This approach could incorporate a broader dimension of preferences, including an explicit consideration of the value of care relative to its cost. Unlike most approximations of adequacy this concept is more amenable to measurement. In fact, a modification of average use—people with similar health conditions receiving the same volume of care at a standard acceptable to middle-class Americans—is now employed by the Robert Wood Johnson Foundation in determining when adequacy is achieved.[32]

Unfortunately, this approach also has its weaknesses. Again, in making choices about health care, patients may inappropriately evaluate those costs that are covered by insurance. Moreover, recognizing their lack of knowledge, patients generally rely heavily on their practitioner's judgment, which as noted earlier may favor care that is disproportionately costly relative to its benefits. On the other hand, if a patient makes an independent choice it may be an uninformed one that rejects care that is actually of significant benefit relative to its cost. Thus, people of average means may lack some care that ought to be part of an adequate level while they receive some care that ought not to be included in it.

Nevertheless, this concept also has a role to play in determining adequacy. In particular, if some of the distorting factors could be lessened, the care sought by well-educated people of average means might be a reasonable benchmark, at least for the treatment of serious conditions.

List of services. Another alternative is to attempt to specify a list of services to be included within an adequate level of health care. An example is the list of "basic health services" in the Health Maintenance Organization (HMO) Act of 1973 (as amended), which includes physician services, inpatient and outpatient hospital services, emergency health services, short-term outpatient mental health services (up to 20 visits), treatment and referral for drug and alcohol abuse, laboratory work and X-rays, home health services, and certain preventive health services.[33]

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[32] Testimony of Robert J. Blendon, transcript of 24th meeting of the President's Commission (Sept. 10, 1982) at 21.

The broad categories on this list might be broken down into more specific services. However, such a list of services is no more a specification of an adequate level of care than a list of foods is an adequate diet. What makes the HMO list into an "adequate level" specification is its combination with a delivery mechanism that relies on professional judgment to determine the appropriate amounts of services on a case-by-case basis, with organizational and financial incentives to weigh the benefits of services against cost. Other approximations in this same spirit include insurance contracts that incorporate reviews of the appropriateness of services received.

Overall evaluation. It would, of course, be possible to combine several approaches—by specifying categories of services that must be available as part of adequate care, for example, while placing limits on the overall use of services through a health insurance package valued at a specified amount. Another variation of this approach would involve an effort by the medical profession to redefine standards of practice to incorporate some assessments of the costs and benefits of acceptable alternative therapies. This might be achieved through medical education, consensus conferences, and other methods. Such determinations would, of course, take place within a process that allowed an interplay between the health care professions and political and other social factors.

The Commission cites these alternatives as examples of possible initial approaches to approximating an adequate level of health care that should be available to all Americans. There are both theoretical and practical differences between these approaches, yet each has something to offer, separately and together. For the purpose of health policy formulation, general theories as well as ordinary views of equity do not determine a unique solution to defining adequate care but rather set some broad limits within which that definition should fall. It is reasonable for a society to turn to fair, democratic political procedures to make a choice among just alternatives. Given the great imprecision in the notion of adequate health care, however, it is especially important that the procedures used to define that level be—and be perceived to be—fair.

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[33] Health Maintenance Organization Act of 1973 (Pub. L. No. 93-222).

Mr. **Gore**. Professor Capron, that is entirely appropriate.

We appreciate the approach you take to these issues. You have helped us on a number of occasions to understand these matters a lot better.

How do you react from a bioethical perspective to the fact that Mr. and Mrs. Fiske were unable to get their child, Jamie, listed as a potential liver recipient until they could assure that the insurance company would pay for the transplant? She was going to die if she didn't get it. They couldn't even get her on the list.

The hospital didn't present it that starkly. I thought his testimony was quite good on that point. They won't present it quite that starkly, but in fact that is what happens. That is exactly what happens.

Captain Broderick yesterday came here with his daughter, who is going to die unless she gets a transplant, and the CHAMPUS program, the Government health care program that takes care of active duty military people and their families, refuses to pay.

Is it unethical for us as a society to say to the parents of these children and to the children themselves, that they have to die because we think the operation is too expensive?

Mr. **Capron**. I think the question is not simply whether it is too expensive. As a human being, I react with compassion and with concern for those people. If I were a physician and being asked to perform a treatment for free, or a hospital administrator and being asked to absorb those costs and pass them on to other people, in effect, that would be a difficult question for me to answer. I believe I would like to say that I would try to help that particular person.

But what we are talking about here in the Commission's view is a standard for making some form of public policy which has to be based on something other than an individualized, compassionate reaction to an individual situation. We need a number of mechanisms through which to judge whether liver transplantation is part of that adequate level of care that society is obligated to insure is provided to everyone?

To do that, there are a number of mechanisms. One is the mechanism which I believe the CHAMPUS program has cited, which is to say is this a procedure which is regarded by physicians as now of proven benefit. Even if someone says I have a technique that might save someone's life, we wouldn't necessarily run to pay for that as part of established medical care until it has some proven benefit.

That is not the end of the discussion, in the Commission's view. That is only one way in which adequacy can be determined. Another is to look at what people would regard as the sort of care they would expect to receive if they were paying for insurance themselves. One of the things about our present insurance system, of course, is that it tends to subsidize the purchase of health insurance so that people have health insurance plans that are much more generous than they would have if they were really comparing health care with other things.

After all, we aren't just talking about medical care to save life. We are talking about the expenditure of our resources on all the aspects of life. So, that is another means of measuring. Already, with some of the changes that have been made in the tax law in the last Congress, we are moving in that direction, of recognizing that subsidized health care through employer, subsidies and so forth may tend to be written at a higher level and lead to extravagance.

Another thing is to compare this particular condition that you are talking about treating, its effect on opportunity and on life, with other conditions and ask how we respond there as a society.

With the precedent established by end-stage renal disease in 1973, the situation really changed. We now have at least one precedent which says that when we have a disease that can be treated in this way, with roughly this sort of expenditure of funds, we believe in making the social resources available. In effect, as a society we are defining that as part of an adequate level. I think that is a decision we have to examine and ask how far we press that.

As I said, we already find physicians having to make choices. The example the Commission gave is that it would not seem justified, although the funding is literally there, to use the resources to treat a patient who goes into kidney failure who is in a permanent state of unconsciousness, because the benefit to the patient would be so small.

So, I believe one has to compare, in talking about whether society has an obligation, the relative benefit of this procedure versus other procedures. It is a matter of beginning with those things about which we have greatest agreement and working outward from there. Liver transplantation now is somewhere on the fringe, not close to the core agreement that we have, but something that we build out from our core agreement.

Mr. GORE. Professor Capron, I get the feeling that maybe there is some sensitivity on the part of the Commission after the reaction to your report on the obligation of society to provide care. At least I hear a great deal of caution in your response.

Mr. CAPRON. I don't mean to be cautious so much as saying that this is not a subject to which I think a simple answer can be given.

Mr. GORE. Let me change the question slightly. If one accepts as fact the testimony of the leading experts in the world, who testified here yesterday, that there is now a 75 percent success rate with this procedure, and if you further accept as the fact the assertion that in many, if not most, of these cases the cost of providing for care up to and until death will exceed the cost of the transplant intervention, which saves that person's life, then is it unethical for us to tell the families of these children that they can't have the operation because society can't afford the up-front cost of the transplant.

Mr. CAPRON. I don't think that this is a forum in which that decision can be made. I can give you my response to it, which is if you are saying that you are already agreeing and obligated to pay so many hundreds of thousands of dollars for care which is merely, in effect, custodial care for a person as they die and isn't providing them any cure, it would seem, just from the viewpoint of saving the money, that it is not a matter of ethics, it is a matter of common sense to say one would prefer to spend the money to give the person a 75-percent chance of then living a normal life.

The problems with reaching a generalization from that is that that is not the case with a lot of the sorts of conditions we are talking about. That, in a way, is a convenient peg to hang that particular example on. Unfortunately, a lot of the examples are not going to fit that way.

A person who is in end-stage renal disease may die quite rapidly. If we didn't have the present program, I think it would be very hard to make that argument. At the time that Dr. Barney Clark died, at his funeral, Wilhelm Kolff, who was the inventor of the artificial kidney and a primary inventor of the present mechanically implanted "Jarvik heart" that was used for Dr. Clark stated, in his view, "We are now ready to give relief to the tens of thousands of victims of heart failure in this country." There will be people who believe that now and who will say since Barney Clark lived for 5 or 6 months, that is a success. Are we prepared now to make that determination for the artificial heart?

I think we have to look at all the facts of a case. In many of those cases we will not have the more convenient out of saying look, it is just good, prudent economics to spend the money to try to give a cure rather than to spend the money to just watch someone die.

Mr. GORE. We will pursue that with our other witnesses, but it seems to me a related issue is how quickly the system responds with updated bioethical judgments to new and different facts, such as a dramatically improved success rate and the new figures on the economics of the procedures involved.

Mr. CAPRON. One ability that the system had prior to 1981 to respond was the National Center for Health Care Technology, which was established in 1978 and had 3 years of life. It was beginning to give exactly that kind of more sophisticated advice to the Health Care Financing Administration and then was eliminated. There are means by which people can give advice of the sort that you are saying so that the system does respond.

Mr. GORE. Let me try one more time. Let me ask the question a little different way. Let's try it one more time and then we will let you go and go to the other witnesses.

Leaving the fact that you can probably save money out of it, here you have got a child. This child is going to die within two months. Her parents don't have the money to pay for the operation. If she gets the operation, she will almost certainly live a normal, healthy, productive life.

We as a country look at that set of circumstances. If we say to the parents of that child, your child must die because we don't feel any obligation to help you finance the operation that will save her life.

In your opinion, if society made that decision, would it be justified in doing so? Let me ask the question a little bit differently. You are telling me, in your responses, that the answer is now clear. You don't think the answer is clearly yes, we have an obligation to save that child's life in those circumstances?

Mr. CAPRON. That is correct. The situation I think is different from the personal obligation because when we make societal judgments like this we establish a statement about our obligations not just toward that one child, but toward many people in the situation. Is the fact that it is a child important in your example, for example? What about a 50-year-old person. What is the difference? It is a human life.

Mr. **Gore**. I am not sure I can define a legalistic distinction. It makes it easier for me to understand it. Maybe that is wrong on my part.

Mr. **Capron**. Whenever you have an example, you have a child who has fallen into a well or a miner trapped in a mine, we will spend tens or hundreds of thousands of dollars to try to get the persons out of the predicament on the possibility that they are alive. People will risk their lives to get that identifiable person.

Of course, when you have a Jamie Fiske or any other identifiable child and the basic statement is that what stands between that child and a chance at life is money, we want to say spend the money. It is small potatoes to the things that are on the walls of this conference room. We spend all that money shooting things up into space, and we are talking about saving a human life.

If it were my decision, sir, my answer would be save that life. But I recognize that we are not just talking about that one child. We are talking about a statistical problem. The fact of the matter is, although we have that compassion, we haven't done a lot yet to make the organs available that are necessary. Why should we be talking about money? Here is something which we can give without cost. I don't know how many people in this room have organ cards. How many people have taken that step?

If we're talking solely about the money, it may well be that the liver transplant situation is the kind of situation where we ought to include that now. We ought to say CHAMPUS, medicare, medicaid and Blue Cross, to the extent that we influence the private programs and so on, yes, they ought to pay. It has established value and it is life-saving and so forth.

I am just saying it is not simply a question of money. We still end up with hard choices as to the indications in any particular case. Moreover, there are other things that society could do. I would like to see us not forget about those as well.

Mr. **Gore**. Thank you very much, Professor Capron. I have too much respect for your judgment not to pause at the fact that I disagree with you slightly on this.

Mr. **Capron**. Why don't you come to my class and we will talk about it there? Then I am sure you will agree with me.

Mr. **Gore**. Thanks anyway.

Dr. Veatch and Dr. Childress, thank you for your indulgence. We will continue the panel with you, Dr. Veatch, the professor of medical ethics and senior research scholar at the Kennedy Institute of Ethics at Georgetown University.

Thank you for your patience and for your willingness to contribute to this hearing.

Mr. **Veatch**. Thank you very much.

I have been asked to review bioethical and religious issues surrounding organ procurement. I am a Methodist, but I want to make clear that I am speaking for no religious or academic group and shall try to present as fairly as possible my understanding of the views of the major groups on the issues at hand.

Furthermore, in the interest of time, I want to limit my remarks to procurement of cadaver organs and I want to summarize at least some of the points that are developed more fully in written testimony.

As I understand the contemporary bioethical debate over organ procurement, it contains two issues that I will label as preliminary and two that are more central. The ethics of the definition of death and the ethics of removal of cadaver organs I take to be preliminary, while the donation versus salvaging controversy and the ethics of fairness in organ distribution I take to be central.

All of the major religious groups reveal some differences of opinion over the shift to the use of brain-oriented criteria for the definition of death. I summarize those in my written testimony. I will skip over them.

Jumping to my summary, at least some responsible members of all of the major religious traditions accept the brain-oriented definition theologically and find it appropriate as a basis for procuring cadaver organs, at least for lifesaving interventions.

There is also substantial ethical agreement on what I described as the second preliminary ethical question, the ethics of the removal of cadaver organs. There has been in general no objection among either the religious or the secular bioethical community to the removal of organs for lifesaving purposes, although there are objections of removing them for other purposes, once it has been established that the patient is indeed dead.

I would like to focus my attention on what I described as the two more critical or central ethical issues.

First, the controversy over donation versus salvaging of organs. It has been recognized for several years that there are really two basic alternatives for organ procurement: donation and salvaging.

It is the second alternative that is favored by virtually every writer within the Judeo-Christian tradition and by every religious group speaking on the subject. The reason is that according to the Judeo-Christian tradition, our respect for the individual and the rights associated with the individual do not cease with death.

In the Judeo-Christian tradition, as opposed, for example, to much Greek thought, the body is affirmed to be a central part of the total spiritual being. Any scheme that abandons the mode of donation in favor of viewing the cadaver as a social resource to be mined for worthwhile social purposes will directly violate the central tenets of Christian thought and create serious problems for Jewish thought as well, at least when Jews are not in a State governed by Jewish law.

At the same time, there is uniform support in all the major religious traditions, not only for the ethical acceptability of donations, but the actual moral obligation to take organ donation seriously.

This suggests that while all traditions would oppose routine salvaging, the kind of scheme Alex Capron was talking about of just taking the organs, these traditions would look favorably upon public policies to make donation as easy as possible.

The public policy implication is that the correct solution to the donation versus salvaging controversy is maximum encouragement to facilitate donation, provided that this does not subtly coerce those unwilling to donate or trick them into donating without realizing it.

The schemes to indicate willingness to donate on State driver's licenses, for example, seem very reasonable. In addition, I would endorse all of the schemes that were proposed earlier, Dr. Ogden's scheme, making this part of routine admission to a hospital.

I would also suggest that we look at the possibility of incorporating organ donation into Federal documents, especially those already computerized for easy retrieval, such as income tax or social security records. This provides, in addition, an opportunity for regular updating of the individual's wishes.

The ideal form of the question about willingness to donate would permit three responses, yes, no, and no response, thus not creating any presumptions or pressures. This strategy seems far preferable to continental European public policies authorizing routine salvaging unless objection has been registered.

It is even preferable to a British scheme, endorsed by the British Working Party of the Health Department in Britain, which would give a designated government or hospital official the power to remove organs for transplant in cases where no objection has been registered and relatives cannot be located.

This group would die alone without relatives available and is sufficient small and sufficiently vulnerable that those formulating public policy should bend over backward to avoid abusing their right to be treated with maximum respect.

This brings me to the fourth and final, perhaps the most critical question of all, that of fairness in distribution of organs once they are procured.

Congressman Gore, in your communication to me about these hearings, you indicated that the subcommittee was particularly interested in looking at approaches to promote efficient distributions of organs for transplant recipients. While those standing within the religious traditions I am attempting to summarize would be concerned about efficient distribution, I think they would place at least equal emphasis on fair distribution.

For example, a Detroit newspaper some years ago carried an ad with an offer to buy kidneys for $3,000 suitable for transplantation. Markets in organs might just turn out to be efficient, but I am convinced that they would be opposed vigorously by the mainstream of the religious traditions I am summarizing.

They would be opposed, among other reasons, because the allocation, though perhaps efficient in maximizing the number of organs transplated, would be grossly discriminatory against those unable to pay.

The Judeo-Christian tradition is deeply committed to distribution on the basis of need. A single dominant theme of both Jewish and Christian ethics has been the responsibility to those in need: The lame, the halt, the blind, and now those in need of organs.

Any allocation scheme that permits other variables, such as ability to pay or some judgment about how socially useful a recipient will be, has been uniformly opposed by all of the commentators working within these traditions.

Some unfair allocation schemes, it turns out, may not be as blatant as direct market mechanisms to buy organs. Current medicare policy, for instance, prohibits funding of heart transplants under Government health insurance and has a similar impact of discriminating against the needy.

It is my sense that spokespeople for religious traditions and the theologians writing within these traditions are realists. They recognize the Government could not make a commitment to pay for all possible medical care. That is precisely the point Alex Capron was making. They do, however, share with the President's Commission the conviction there should be some floor level of health care under which no one ought to fall.

In the allocation of scarce organs for transplant, at least in such cases as hearts, kidneys, and livers, where the organs are literally lifesaving, allocation is simply unfair if it is based on ability to pay.

If anyone has access, all should have an equal chance, either by some lottery system, random assignment of organs to those in equal need, or by some randomness of having to wait in line for needed organs.

That is the conclusion reached by virtually every theologian working in the tradition I am summarizing. No one should get an organ for transplant or an artificial organ for implant until there is a fair, nondiscriminatory allocation system in place which gives everyone any equal need for lifesaving organs an equal opportunity for access.

Recently, we have discovered even more subtle problems of fair and efficient allocation. What I have to say here is perhaps a bit sensitive, and I want to state my views very carefully.

Some individuals with particular skills in reaching the medical profession or the mass media or have been able to procure organs for themselves or for their family members. Candice Thomas was here earlier this morning. Those supporting her care, according to a fundraising campaign on a local radio station, have gotten President Reagan to volunteer an airplane, presumably Air Force One, to transport any donated liver.

No one can possibly criticize these parents for doing everything possible to meet the needs of their loved ones. In fact, they have probably increased the efficiency in organ procurement by reaching organs that would otherwise go to waste and by increasing public awareness.

As a society, however, I believe we should be ashamed that these people are forced to use ad hoc techniques, personal charisma and persuasion to obtain organs for their families. It is simply too disorganized, too ideosyncratic a method. It is unfair to the families in crisis. It is unfair to those who lack the power or the access to those means of getting organs.

Either the use of government airplanes to meet these needs is justified, and it should be done for all in need of organs, or it is not, and it should not be done for any. A much more systematic, institutional response is called for, one that in a disciplined way makes available every organ within reach donated by a patient or the responsible next of kin in a manner that gives all people of equal need equal opportunity of access. I think that the Federal Government is the only institution that can provide that kind of systematic, fair access.

Some such organized system of fair access is called for by Jewish and Christian traditions that I have been asked to summarize. In principle, it seems to me that it is the public policy that has to be recommended to this committee.

Thank you.

Mr. **Gore**. Thank you very much. That is very thoughtful and helpful testimony. We will hold questions until Dr. Childress has rounded out the panel.

[The prepared statement of Dr. Veatch follows:]

STATEMENT OF ROBERT M. VEATCH

My name is Robert Veatch. I am the Professor of Medical Ethics at Georgetown University's Kennedy Institute of Ethics, a research center devoted to studying the social and ethical aspects of medicine and health policy. I have graduate level training in neuro-pharmacology, a divinity school degree from Harvard, and a doctorate in the study of religion and society at Harvard where I concentrated in medical ethics. I have been asked to review the bioethical and religious issues surrounding organ procurement. Although I am a Methodist, I speak for no religious or academic group and shall try to present fairly my understanding of the views of major religious groups on the issues at hand.

The bioethical debate over organ procurement goes back at least to the first kidney transplants in 1954. The current generation of controversy, however, can be dated from December 3, 1967, when Christiaan Barnard transplanted the first human heart into the chest of Louis Washkansky. In what follows I limit my remarks to the procurement of cadaver organs. While organ procurement from living donors, especially related donors, appears to be acceptable in cases where the transplant would be life-saving for a recipient and would not be life-threatening for the donor, there is widespread disapproval of procuring organs from living donors when the removal of the organ would be life-threatening.

In any case, I assume that cadaver organ procurement constitutes the critical ethical and public policy problem. It is here that the most good can be done by clarifying our ethical and religious requirements.

As I understand the contemporary bioethical debate over organ procurement, it contains two issues I shall label as preliminary and two issues that are central or core. The ethics of the definition of death and the removal of cadaver organs I take to be preliminary while the donation vs. salvaging controversy and the ethics of fairness in organ distribution I take to be central.

All major religious groups reveal some differences of opinion over a shift to the use of a brain-oriented definition of death, a shift important if organ procurement is to be facilitated. Within Judaism there has been the greatest resistance to shifting to a brain-oriented defintion of death. Rabbi David Bleich, philosopher at Yeshiva University, for example, opposes any shift, saying that "the patient cannot be pronounced dead other than upon the irreversible cessation of both cardiac and respiratory activity."[1] On the other hand, other Rabbis from Conservative and Reformed traditions have endorsed the use of brain criteria for death pronouncement.[2]

Among Catholics Pope Pius XII opened the door for a shift in the definition of death in 1957 saying, "it remains for the doctor, and especially the anesthesiologist, to give a clear and precise definition of 'death' and the 'moment of death' of a patient who passes away in a state of unconsciousness."[3] There have never been any principled theological objections to a brain-oriented definition of death among Catholics although occasionally more conservative Catholics, often those associated with right-to-life positions, have expressed fear that acknowledging that a person is dead when the brain is dead might indirectly lessen respect for those who are still living.[4]

Protestant theologians (and Protestant groups when they have spoken on the subject) have almost uniformly favored some brain-oriented definition of death whether they represent more conservative[5] (Paul Ramsey) or liberal[6] (Joseph Fletcher) perspectives. Thus while there is some concern about the use of a brain-oriented definition of death, at least some responsible members of all major religious traditions accept it theologically and find it appropriate as a basis for procuring cadaver organs.

More significantly, there is substantial ethical agreement on the second preliminary ethical question, the ethics of removal of cadaver organs. There has in general been no objection among either the secular or religious bioethical community to the removal of organs for life-saving purposes from human bodies once it is established those persons are dead. Protestants and Catholics have raised no serious questions about cadaver organ removal provided appropriate respect is shown for the deceased and appropriate permissions are obtained.[7]

Jewish thought poses a more serious question since in Judaism there are religious obligations to bury the dead with organs intact.[8] This obligation is superseded when a cadaver organ can be removed for the purpose of saving a life of another identified person in need. Thus all major religious traditions accept the legitimacy of removing cadaver organs for life-saving transplantation. Some may insist on more conservative heart-and-lung-oriented criteria for death and some, especially Orthodox Jews, may object to organ removal for research or educational purposes, but the two preliminary ethical problems pose no insurmountable obstacles for cadaver organ procurement. In fact, they all place a high value on the saving of human life so that while the state may not be authorized to salvage organs routinely, individuals bear at least a moral obligation to facilitate organ procurement for life-saving purposes.

This brings us to the two more critical and controversial core ethical issues. First, the controversy over donation vs. salvaging of organs. It has been recognized for years that there are two basic alternatives for organ procurement: donation and salvaging. Under salvaging schemes, such as that proposed by Dukeminier and Sanders, cadaver organs would be routinely made available as needed as a social resource.[9] Normally, advocates of salvaging would permit individuals to object in writing while living or even permit relatives to object in cases where the individual has not expressed his or her wishes. The other alternative emphasizes donation.

It is this second alternative that has been favored by virtually every writer within the Judeo-Christian tradition and by every religious group speaking on the subject.[10] The reason is fundamentally that according to the Judeo-Christian tradition, our respect for the individual and the rights associated with that individual do not cease at death. Obligations of respect--for the wishes of the deceased and the integrity of his earthly remains--must continue. In the Judeo-Christian tradition, as opposed to much pagan Greek thought, the body is affirmed to be a central part of the total spiritual being. Any scheme that abandons the mode of donation in favor of viewing the cadaver as a social resource to be mined for worthwhile social purposes will directly violate central tenets of Christian thought and create serious problems for Jews as well, especially in a state not based on Jewish law. It will, more pragmatically, predictably produce vociferous, agitated opposition. While I cannot predict street riots comparable to those sparked in Israel after the passing of autopsy laws permitting routine violation of the corpse,[11] it is safe to say there would be sustained and vocal opposition.

At the same time there is uniform support in all major traditions not only for the ethical acceptability of donation, but the actual moral obligation to take organ donation seriously. This suggests while, for practical and theoretical reasons, all traditions would oppose routine salvaging, they would look favorably upon public policies to make donation as easy as possible. Given the fact that these religious traditions all support organ donation in at least some circumstances and in fact consider it a morally weighty obligation, they would favor public policies making it as easy as possible to express a willingness to donate organs for life-saving purposes.

The public policy implication is that the correct solution to the donation vs. salvaging controversy is maximum encouragement to facilitate donation, provided this does not subtly coerce those unwilling to donate or does not trick them into donating unintentionally. The schemes to indicate willingness to donate on state drivers' licenses, for example, would seem very reasonable. In addition, questions on federal documents, especially those already computerized for easy retrieval such as income tax or social security records, would seem appropriate. The ideal form of the question about willingness to donate would permit three responses--yes, no, and no response--thus not creating any presumptions or pressures on any respondents. This strategy seems far preferable to continental European public policies authorizing routine salvaging unless objection has been registered.[12] It is even preferable to the scheme endorsed by the British Working Party of the Health Departments of Great Britain and Northern Ireland, which would give a designated government or hospital official the power to remove organs for transplantation in cases where no objection has been registered and relatives cannot be located.[13] This group who die alone, without relatives available, is sufficiently small and sufficiently vulnerable that those formulating public policies should bend over backwards to avoid abusing their right to be treated with maximum respect.

This brings us to the final critical question: fairness in the distribution of organs once they are procured. Congressman Gore, in his communication to me about these hearings, indicated that the subcommittee was particularly interested in looking at approaches to promote efficient distribution of organs to transplant recipients. While those standing within the religious traditions I am attempting to summarize would be concerned about efficient distribution, I think it is clear that they would place at least equal emphasis on the problems of fair distribution.

For example, there have from time to time been casual references to the use of market mechanisms to promote efficient transfer of organs to recipients. A Detroit newspaper some years ago carried an ad with an offer to buy a kidney for $3,000.[14] Markets in organs might turn out to be efficient, but I am convinced they would be opposed vigorously by the mainstream of these religious traditions. They would be opposed because the allocation, though perhaps efficient in maximizing the number of organs transplanted, would be grossly discriminatory against those unable to pay. The Judeo-Christian tradition is deeply committed to distribution on the basis of need. The single dominant theme of both Jewish and Christian ethics has been the responsibility to those in need--the lame, the halt, the blind, and those in need of organs. Any allocation scheme that permits other variables such as ability to pay or some judgment about how socially useful a recipient will be has been uniformly opposed by all commentators working from within these traditions.[15]

Some unfair allocation schemes may not be as blatant as direct market mechanisms to buy organs. Current Medicare policy prohibiting funding of heart transplants under government health insurance has a similar impact of discriminating against the needy.[16] It is my sense that spokespeople for religious groups and theologians writing within these traditions are realists. They recognize that the government cannot make a commitment to pay for all possible medical care. They do, however, share with the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research the conviction that there should be some floor level of health care under which no one ought to fall.[17] In the allocation of scarce organs for transplant, at least in cases such as hearts, kidneys, or livers, where the organs are literally life-saving, allocation is simply unfair if it is based on ability to pay. If anyone has access, all should have an equal chance, by some lottery system, random assignment of organs to those in equal need, or by the randomness of having each wait in line for needed organs. That is the conclusion reached by virtually very theologian writing out of the Judeo-Christian tradition and, I am convinced, the only one they can reach and be consistent with that tradition's commitment to equal treatment based on need. No one should get an organ for transplant (or an artificial organ for implant) until there is a fair, non-discriminatory allocation system in place which gives everyone in equal need for life-saving organs an equal opportunity of access.

Recently we have discovered even more subtle problems of fair and efficient allocation. Some individuals with particular skills in reaching the medical profession or the mass media have been able to procure organs for themselves or their family members. Those supporting a small child in need of a liver transplant have even, according to a fund-raising campaign for a local radio station, gotten President Reagan to volunteer Air Force One to transport any donated liver. No one can possibly criticize them for fulfilling their obligations to themselves and their loved ones to do everything reasonable to serve their needs. In fact, they probably increase efficiency in organ procurement by reaching organs that may otherwise go to waste and by increasing public awareness of the need for organs. As a society, however, the use of such ad hoc techniques of personal charisma and persuasion to obtain organs should be viewed with skepticism. It is simply too disorganized, too idiosyncratic a method. It is unfair to those who lack the power or access to these means of obtaining organs. Either the use of government airplanes for organ transportation is justified and it should be done for all organs, or it is not and and it should not be done at all. A much more systematic, institutional response is called for, one that in a disciplined way makes available every organ within reach donated by the patient or the responsible next of kin in a manner that gives all people of equal need an equal opportunity of access. I think the federal government is the only institution that can provide that kind of systematic, fair access. Some such organized system of fair access is called for by the Jewish and Christian traditions that I have been asked to summarize. It is the principle of a public policy that I would recommend to this committee.

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15. Gene Outka, "Social Justice and Equal Access to Health Care," *Journal of Religious Ethics* 2 (Spring 1974): 11-32; James F. Childress, "Who Shall Live When Not All Can Live?" *Soundings* 53 (Winter 1970): 339-54.

16. U.S. Health Care Financing Administration, "Exclusion of Heart Transplantation Procedures from Medicare Coverage," *Federal Register* 45 (August 6, 1980): 52296-97.

17. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Securing Access to Health Care: The Ethical Implications of Differences in the Availability of Health Services*. Vol. 1: Report (Washington, D.C.: U.S. Government Printing Office, March 1983), p. 4.

Mr. GORE. Dr. Childress, we are honored to have you here today. We invite you to proceed.

Dr. CHILDRESS. Mr. Chairman and members of the committee, thank you very much for this opportunity to testify.

So far, our society has failed to provide an adequate supply of organs that can be transplanted to save many lives, but this scarcity is not absolute, as we have heard today. Each year in the United States there are more than enough deaths, under conditions that would permit the salvage of organs, to provide a surplus of organs; there are approximately 20,000 such deaths. Unfortunately, most of those organs are wasted.

It is not too difficult, as we have heard today, to secure organs for dramatic cases involving identified lives, such as Jamie Fiske, but not everyone can generate that publicity. It may be necessary—indeed, I think it probably is—to change our policies in order to increase the supply of organs for unidentified strangers.

The question is whether we can increase the supply of organs for transplantation, which is an ethically desirable goal and, as Professor Veatch has reminded us, is consistent with the Judeo-Christian tradition, without violating other important moral principles and values, such as respect for persons and their wishes and principles of justice or fairness in the distribution of benefits and burdens in the society.

I want to concentrate on obtaining cadaver organs and then make a few comments about living donors before concluding by identifying some other problems that we need to face.

First, cadaver organs. Currently, in all 50 States, under the Uniform Anatomical Gift Act, individuals may sign a donor card to consent to the use of their organs after their deaths or their families may consent.

Although there is a lot of controversy about this, according to the studies I have seen, very few people—the studies indicate between 1.5 percent and 19 percent—ever bother to sign their donor cards. It may be very difficult for physicians to ask a family for permission or for the family to grant permission after the patient has died, if the patient has not earlier indicated his or her wishes.

Several possible approaches have been suggested for obtaining cadaveric organs. The first would be to keep the Uniform Anatomical Gift Act as it is, but to educate the public and to educate and to organize professionals in order to obtain more organs.

I would agree with the emphasis on education of the public and education of professionals. It is not at all clear how effective this will be, but it will nevertheless be very important within any acceptable policy.

Regarding organization, the Centers for Disease Control studied the establishment of a recruitment network that over a 3-year period had a remarkable success rate of increasing the donation of organs by eight- or nine-fold.

I think it is important to note in that particular study that approximately 50 percent of the families who were asked to donate organs of their deceased relatives refused to give consent. Thus, in addition to organization, I think we will need to pay some attention to revisions in the Uniform Anatomical Gift Act.

Two such revisions might be considered. First, we might require a decision for or against organ donation of all adults. I don't think there can be a major ethical objection to this policy. It is consistent with principles of respect for persons and justice to require people to make a decision for or against donation. They would not be forced to decide for donation; they would only be forced to make a decision.

Second, I would even be willing to consider from an ethical standpoint the possibility of moving to a system of presumed consent, the so-called routine salvaging of organs or harvesting organs, except where there has been prior objection by the deceased person or where there is objection by the family.

This is the system that has already been described as contracting out rather than contracting in.

Mr. **Gore**. Opting out, I think.

Dr. **Childress**. Both contracting out and opting out. Both terms are used interchangeably.

Mr. **Gore**. Thank you.

Dr. **Childress**. This is the practice in several countries, including Denmark, France, Israel, Italy, Norway, Spain, Sweden and Switzerland, among others. Sometimes this system of opting out or contracting out is combined with the use of donor cards and with attention to family objections.

In the countries mentioned there are still some shortages of organs, but they come closer to meeting the needs, for example, for transplant kidneys than our own country does.

I think all three approaches to obtain cadaveric organs are ethically acceptable—the Uniform Anatomical Gift Act, requiring a decision, or presuming consent. They all seek a morally desirable goal without violating fundamental moral principles.

Nevertheless, I agree with Robert Veatch that it would be ethically preferable to keep the Uniform Anatomical Gift Act, the policy of giving and receiving that emphasizes voluntary generosity and altruism, other things being equal. But I think that this policy has not proved to be adequate to meet our needs.

Next in rank order, but still ethically acceptable, would be a policy of requiring a decision and finally a policy of presuming consent. I would emphasize that I believe they are still ethically acceptable even if the Uniform Anatomical Gift Act is preferable.

Then I think we should consider which one of these might be the most effective and efficient in obtaining organs as long as, again, we are not violating fundamental ethical principles. It would, however, be ethically unacceptable simply to take organs without regard to prior wishes or current objections. No one really proposes that.

A few comments about living donors, who are especially important in kidney transplantation and bone marrow transplantation. For example, in renal transplantation approximately 30 percent of the kidneys come from living donors, most often living-related donors.

In general, the trend over the last several years away fom the use of kidneys from living donors is to be applauded because it avoids risks to healthy persons. But in some situations living donors, especially related living donors, may be the best sources, if we can be sure that those donors are competent to consent, are informed, and are choosing voluntarily. To exlude them categorically would be unwarranted paternalism. Yet, a policy of obtaining or seeking cadveric kidneys wherever possible is morally preferable.

In my written testimony, I discussed two classes of family members who are especially problematic as donors: Preadolescent children and mentally retarded persons. I will not discuss them here.

Let me make one comment about living, unrelated donors. Few kidneys from such donors have been accepted since 1970, perhaps because of a widespread suspicion that such persons are unbalanced because they want to make such a donation to people who are not their relatives and who are perhaps even strangers.

Yet, some polls indicate that approximately half of the people interviewed think that there is an even chance that they would donate a kidney to a stranger while they are alive. So, I think we should not categorically exclude such individuals if, again, they are competent, informed, and choosing voluntarily.

Regarding the sale of organs from living donors or from newly dead persons, neomorts as they are sometimes called, I think it is important to note that the sale of organs is not clearly prohibited in most states. It has been reported in other countries, and there are advertisements, as already noted, in many places in the United States.

I think that the sale of organs should be prohibited for the reasons that Professor Capron indicated, especially to prevent abuses and to prevent exploitation in a society with great differences in the distribution of wealth.

Finally, let me identify a couple of problems that need further attention.

First, people frequently do not sign their donor cards because of forgetfulness. Furthermore, less than 20 percent of the population at large have wills when they die. I think that in the area of organ donation there is also the element of fear and distrust of medical professionals and institutions, fueled perhaps by such movies as "Coma." There is a fear of being declared dead prematurely in order to benefit others.

I am not sure that the educational and organizational procedures suggested earlier or the changes proposed in the Uniform Anatomical Gift Act would really reduce fear and distrust. I am not sure how this can be done, but I think it is an important problem if we are really going to increase the supply of organs.

Mr. GORE. Doctor, I think that is an important problem, too. Even if it is often unstated or unarticulated, I think that is in the back of the mind of a lot of people who use it not as a factor in making an explicit decision but as almost an unconscious factor in deciding not to decide, in not facing the question because of that lingering doubt or fear.

Do you agree with that?

Dr. CHILDRESS. I do, indeed. Earlier this week I was making a presentation at the West Virginia University Medical Center and had a chance to talk to several chaplains who are involved not only in hospital care, but also in local congregations. They have faced such problems with members of their religious communities, and they reported that fear and distrust emerge again and again in the reservations their parishioners have about organ donation.

Mr. **Gore**. Yesterday we heard some statistics showing that according to the National Kidney Foundation's new Gallup poll, the percentage for black Americans who felt like they might become donors was just half that of the percentage of white Americans.

It occurred to me at that time that the historical and traditional view of society's institutions that is unique to the black community might have contributed to that feeling that we were just discussing and might account for the dramatic difference in the polling results.

Dr. **Childress**. I think that is a very important observation. It would be interesting to know if other people who feel themselves similarly on the margins of society, perhaps economically dispossessed, would have similar reservations or little confidence in the medical profession and institutions in society.

Mr. **Gore**. It seems to me that as the medical community decides how it is going to approach this question—and some of the doctors here yesterday said that the medical community itself has to do a great deal more—it ought to at least consider how it might address that lingering fear and come up with some sort of absolutely fail-safe guarantees that there will be no basis whatsoever for those fears and get that message out. It might really be a bottleneck in holding back the solution to this problem. It is something that I think is worth a good deal of attention.

Dr. **Childress**. I think so, and the mere provision of information that I talked about under the heading of education would not be sufficient. Something else has to occur. We might note that historically the move to update the criteria for determining death was in part influenced by the need to obtain organs for transplantation. That influence was enough to create some suspicion and distrust on the part of individuals.

Mr. **Gore**. There is a movie out now, I haven't seen it yet, and I don't know if anyone has seen the new Monty Python movie. Often humor plays on some unconscious fears. I am told, although I haven't seen it, that one of the skits in the movie is someone walking up and asking individuals if they have an organ donor card. When they respond positively, the character pulls out a gun and shoots him right on the spot. This is presented as a humorous skit in this movie.

The reason it is humorous I think probably has to do with this lingering attitude that probably does play a significant role here.

Please go ahead.

Dr. **Childress**. I will finish with some comments about one more problem; that is the problem of the allocation of society's resources and the allocation of scarce organs. Professor Capron raised this issue. I am not sure where I come down on this issue, but I would agree with him that it is complicated and needs the most careful attention.

For example, society now provides practically universal coverage for renal dialysis and renal transplantation. That decision was made in the early seventies, and now a lot of people are raising questions about whether our society can afford the tremendous costs of the program.

I would suggest that in all of these areas of technology and transplantation it is important to ask the question about how society's scarce resources should be allocated, for example, as Professor Capron suggested, between health care and other goods.

But also, within health care, should we concentrate on technologies for cirtical care or chronic care, or should we concentrate on prevention? It seems to me that this is the kind of question that would have to be faced in an overall societal policy about health care because we might be able to save more lives statistically in the long run if we concentrated on prevention rather than on some forms of critical care. This issue would have to be settled at on a case-by-case basis.

It is important to build on the kind of compassion you described, but also to see how that compassion has to be filtered through a perspective that considers the whole range of health problems in the society and statistical as well as identified lives.

In terms of the other part of the allocation question—the allocation of organs to recipients when the supply is limited—I think that we probably have had fewer problems in this area than in the allocation of artificial organs partly because to allocate organs for transplantation it is necessary to get a good match, that is, to look at the medical need, but also to look at the probability of a successful transplant. Thus, there is a tendency to emphasize medical criteria.

I think that these criteria are important and acceptable, but when we have to move beyond medical criteria, as Professor Veatch has rightly indicated, we should not make judgments of social worth or social value. We should rather use some form of randomization or queuing or "first come, first served" in order to build in a kind of equality of opportunity that respects persons as persons and accords them equal value.

Thank you very much.

[The prepared statement of Dr. Childress follows:]

The Gift of Life: Ethical Problems and Policies in Obtaining Organs for Transplantation

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Several transplanted organs and tissues can increase a recipient's chances of survival or improve a recipient's quality of life. Yet the supply of organs and tissues is inadequate to meet the need and demand for transplantation. Enough cadaveric organs exist, but the society has not yet found an effective, efficient, and morally acceptable way to obtain them. The Council of Scientific Affairs of the American Medical Association has helpfully described our situation:

> Organs removed from a cadaver after breathing and heart action have ceased have sustained serious ischemic injury and, except for cornea, bone, and skin, are rarely suitable for transplantation. Death from brain injury, tumor, or infraction may permit hours or days of normal circulation, especially if controlled mechanical ventilation is maintained, which will allow preservation of heart and kidney until they can be removed, cooled, and properly preserved for transplantation. There are more than enough deaths in the United States (estimate, 20,000) to provide a surfeit of organs, if there were a satisfactory method of bringing all such cadavers into the pool of donors. Now that there is a cadaver graft survival of transplanted hearts or kidneys of 50% to 70% and kidney host survival of up to 90% for two years, it has become important that our society find ways to improve donor recruitment.[1]

Such a dramatic case as Jamie Fiske's can temporarily direct the public's attention to the need for organs. Many potential donors respond enthusiastically to dramatic cases involving *identified lives*, but changes in public policies may be necessary to increase the supply of organs for *unidentified strangers*. Some changes in policies can be expected to increase the supply of organs and tissues and can be implemented without violating important ethical principles and values.

Currently in all fifty states the Uniform Anatomical Gift Act allows us to determine what will be done with our organs after our deaths. If we do not sign a donor card, available in many states with the driver's license, our families may consent to donate our organs after our deaths. According to some opinion polls, as many as 70% of the adult population say that they are willing to have their organs used for transplantation after they die, but very few (between 1.5% and 19%, according to some studies) actually sign donor cards.[2] Furthermore, families frequently find it very difficult to donate organs after the death of a loved one, and physicians and other health care professionals may be reluctant to raise the question of organ donation.[3] In this situation, which policies might increase the supply of organs - a morally desirable goal - without violating other moral principles and values?

In assessing various policies, I will emphasize the following moral principles and values: (1) Not harming others (sometimes called the principle of nonmaleficence); (2) Benefitting others (sometimes called the principle of beneficence); (3) Producing the greatest good for the greatest number (sometimes called the principle of utility); (4) Distributing benefits and burdens in a fair or equitable way (sometimes called the principle of justice); and (5) Respecting personal wishes, choices, and actions (sometimes called the principle of autonomy or the principle of respect for persons). I cannot argue for these principles here, but they are widely accepted as morally relevant to an assessment of actions, practices, and policies in science, medicine, and health care. They can be discerned in various deliberations about policies; for example, they appear (in somewhat different form) in the deliberations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[4] Proposals to change policies in order to increase the supply of organs usually appeal to principles #1, 2, and 3, particularly utility. Arguments against such policies frequently appeal to principles #4 and 5, particularly autonomy or respect for persons. Thus, while all of these principles are relevant to the policies under consideration, I will concentrate on utility and autonomy or respect for persons.

I will argue that an effective and efficient system for obtaining cadaveric organs (organs from the "newly dead" or "neomorts") can reduce and perhaps even eliminate scarcity without violating other principles such as justice and respect for persons. Within the range of ethically acceptable systems of organ procurement, some may be ethically preferable or ideal without being mandatory. It may be *ethically preferable* to retain our current laws regarding organ donation and to reduce scarcity through educational and organizational efforts. But such educational and organizational efforts, which would be expensive, would probably need to be supplemented by changes in the Uniform Anatomical Gift Act. It would be *ethically acceptable* to (a) require each adult to make a decision about the use of his or her organs after death, or (b) to presume consent to organ removal after death unless the person has previously registered his/her dissent or his/her family dissents. It would be *ethically unacceptable* simply to take organs from the decedent without regard to the decedent's prior wishes or the family's wishes. After considering ethically acceptable approaches to obtaining cadaveric organs, I will examine policies regarding living donors.

Cadaveric Organs: Educational and Organizational Efforts within the Current Legal Structure

Education of the public. Policies of educating the public about the need and importance of gifts of life should not be underestimated. Some people fail to sign their donor cards because of forgetfulness; others may mistrust medical institutions and professionals, fearing that they will be declared dead prematurely so that their organs can be retrieved for others. There is a clear need for educational activities that would alert the public to the need for organs and explain the whole process, including the determination of death. Nevertheles such educational activities cannot be expected to reduce scarcity significantly without other changes.

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Education and Organization of Physicians and Other Health Care Professionals. Physicians and other health care professionals need to be educated about the need for organs for transplantation so that they will actively seek to increase the supply. It is not easy for physicians who have "lost" a patient to start thinking about how that dying or dead patient's "parts" might benefit others. Nevertheless, once it is clear that the patient will not survive or is brain dead, the neurosurgeons and neurologists (who see most potential donors) should actively seek to benefit other patients by alerting the appropriate team. As some commentators have argued, "the only goal of the neurosurgeon must be the full treatment of a potentially salvageable patient, [but] once brain death has occurred a more general responsibility become operant, namely to identify potential donors and avoid wastage of organs."[5]

This educational activity needs to be combined with organizational activities to increase the identification of potential donors and to arrange transplantation. The value of organizational activities can be seen in the study of a group of physicians at the Centers for Disease Control in Atlanta. These physicians organized a "recruitment network" to relate the transplant team to certain hospital areas, such as the intensive care units, through a transplant nurse-coordinator. During the 2 1/2 year study, the number of actual donors increased by ninefold.[6]

Obviously, both educational and organizational activities are expensive. Successful efforts will be costly, and they will presuppose some judgments about priorities in the allocation of resources within the health care system. It would be inadequate to undertake one effort without the other. For example, in the CDC study, family consent was received only about half of the time.[7] Hence it is necessary to combine education of the public with education and organization of health care teams. But both would be more effective if donor laws required a decision about donation by all adults or presumed consent from adults who have not objected (or whose families do not object).

Cadaveric Organs: Changes in the Uniform Anatomical Gift Act

Two possible changes in the Uniform Anatomical Gift Act merit careful attention; either could help to increase the supply of organs for transplantation without violating principles of justice or respect for persons.

Requiring a decision. If few donor cards are signed because of inadvertence or forgetfulness, the law could be changed to require everyone above a certain age to make a decision for or against the use of his/her organs after death. Our society rightly wants to avoid making people decide to donate their organs, but there is no ethical objection to requiring them to make a decision for or against such donation. Obviously, such a change in state laws might not lead to a dramatic increase in affirmative decisions about organ donation without the educational efforts mentioned above. Furthermore, the increased use of organs would depend on increased professional activity and organization. But in conjunction with efforts to educate the public and to educate and organize physicians and others, this change in legislation could be very effective. And it does not violate standards of justice and respect for persons; indeed, personal wishes and choices are determinative.

Presuming consent (sometimes called "routine salvaging of organs" or "harvesting organs"). Both the Uniform Anatomical Gift Act and a law requiring a decision involve "contracting in," and both should be ranked above this system of "contracting out."[8] But a system of presumed consent is not ethically unacceptable. Recognition of presumed consent (or tacit consent) as the basis for organ removal after a person's death does not violate principles of justice and respect for persons, if that person had an opportunity to dissent. It has been argued that "presumed consent would ... be in keeping with traditional humanist values by making the basic presumption one that favors life and by putting the burden of objecting upon those who would deny life to another. The policy of saving human life would be given first priority, yet the wishes of persons to preserve a corpse inviolate would also be accommodated."[9] In short, presumed consent (or tacit consent) enables the society both to realize utility and to respect persons. Even though presumed consent would not emphasize voluntary gifts (as in the Uniform Anatomical Gift Act or a statute requiring a decision), it would not authorize actions against a person's express wishes.

Presumed consent laws exist in a number of countries, including Denmark, France, Israel, Italy, Norway, Spain, Sweden, and Switzerland. In approximately half of the countries with presumed consent statutes, physicians also determine whether the family has an objection to organ removal. Some countries recognize both donor cards and presumed consent.[10]

How effective are presumed consent laws in reducing scarcity of organs for transplantation? All countries with presumed consent laws still have waiting lists for renal transplantation, but they "seem to come closer to meeting their needs for transplant kidneys."[11] Presumed consent will probably not be effective without vigorous efforts to educate physicians and other health care professionals and to organize procurement of organs. It will not be ethically acceptable without education of the public about the options, and widespread objections ("opting out") can be expected unless the public realizes the need for organs and trusts the medical profession and institutions. Finally, at least in the United States, a policy of presumed consent ought to be combined with donor cards and family approval. But a policy of presumed consent should make it easier to seek and to gain family approval.

Living Donors

So far I have concentrated on cadaveric organs, examining current and possible policies to increase the supply of such organs and ranking those policies according to several moral principles. But for some tissues and paired organs, such as kidneys, it is possible to use living persons as donors. Some recent controversial cases have involved bone marrow transplantation. In one such case a judge refused to order a man to complete the tests he had started and to donate bone marrow to save his cousin's life if he proved to be histocompatible.[12] The principle of respect for persons, and derivative rules such as privacy, dictate a policy of not removing tissues or organs from a person's body against that person's will even to save someone else's life. This principle is recognized in both morality and law. It is sometimes interpreted to permit removal of organs from an incompetent person, such as a minor or retarded person, but often in those cases the explicit rationale is that the "donor" will also benefit (e.g., by not losing a close sibling). In such cases, proxy consent is required.

In the area of renal transplantation, there has been a clear trend to accept fewer donations from living persons. For example, in 1967, 56% of the transplanted kidneys came from cadavers, while in 1973, 70.4% came from cadavers.[13] That trend has continued. On the one hand, that trend should be applauded insofar as it avoids risks to the health of living donors and risks of manipulation and coercion within a family to get a reluctant donor to give a kidney to a family member. On the other hand, that trend may represent unwarranted disrespect for a potential donor's wishes and choices, which may be adequately informed and voluntary.

The reluctance to use living donors may stem from beliefs about the risks of kidney donation, from worry about the lack of understanding and voluntariness of potential donors, and from fear of malpractice suits. Removing a kidney from a living donor is an atypical medical procedure: It is performed to provide medical benefit for another patient, not for the donor himself or herself. Thus, the risk-benefit calculus mainly involves medical risks for the donor and medical benefits for the recipient (though there may, of course, be nonmedical benefits for the donor and medical risks for the recipient). While kidney donors accept risks from the surgical removal of a kidney as well as from living with only one kidney, their survival rates do not appear to differ from those of nondonors.[14] Furthermore, a competent and informed donor may voluntarily accept such risks without paternalistic intervention. Of course, many potential living donors may be incompetent to consent to such a procedure or may be under severe pressure and even coercion especially within a family context. Such persons generally should not be accepted as donors.

Where the risks are minimal to a particular donor, who is competent, informed, and willing to donate, a signed consent form should be sufficient to protect the physician from a malpractice suit.

While these points hold, in general, for both living related donors and living nonrelated donors, it is useful to distinguish the two groups.

Living related donors. In general, "donor grafts from siblings and parents show superior functional success over cadaver grafts."[15] But this source could not meet the need for kidneys in the population: "Eighty per cent of potential recipients have relatives who are unsuitable donors because of antigenic incompatibility, kidney disease, and renal anatomical problems."[16] Thus, living related donors constitute an important but insufficient source of kidneys for transplantation.

The major ethical concerns about living related donors who are competent to consent focus on their understanding of the risks and their willingness to undergo the surgical procedure and to accept the risks. Some studies show that family members frequently decide to donate a kidney when they hear that a relative needs one, even before they have been informed about the risks. Furthermore, such donors frequently use the language of "necessity" to describe their choice: "I could not have lived with myself if I had failed to donate," or "I had no choice."[17] Neither deciding before being informed nor using the language of necessity invalidates the consent. The donors may have decided that their reasons for donating (e.g., to save a relative's life) outweighed the risks that were disclosed to them, and their language of necessity may simply indicate the importance of their reasons for donation. Of course, judgments about the adequacy of a donor's information, understanding, and voluntariness can only be made in the situation, and professionals need to be sensitive to inadequacies on any of these levels, perhaps especially to subtle signs of coercion from other members of a family. In such settings, physicians sometimes provide a "medical excuse" for potential donors under severe external pressure to donate.[18]

Two classes of living related donors are especially controversial because their autonomy is seriously limited and even nonexistent in some cases: children (especially preadolescent children) and mentally retarded persons. Because of the limitations on their capacity to give valid consent, it may be unjust to impose the burdens and risks of kidney removal on them in order to benefit some other member of the family. The counterargument is that even though children and mentally retarded persons lack the capacity to give valid consent to organ removal, they can sometimes assent to (or dissent from) such a procedure, and, more importantly, they frequently derive significant nonmedical benefits from "organ donation." These benefits may result, for example, from the survival of a family member who contributes greatly to the "donor's" well-being and happiness.[19] There are reasons to be suspicious of claims about such benefits in many cases, but it is unclear to me whether all uses of children or mentally retarded persons as "organ donors" for other members of the family should be categorically prohibited. At the very least, there should be independent, judicial review of the proposal to remove an organ from such an incompetent, dependent, and vulnerable person. This review should determine whether the heavy presumption against using such a person as a "donor" can be rebutted, perhaps because of significant nonmedical benefits to him or her.

Living nonrelated donors. There has also been a trend away from the use of living nonrelated donors. Since 1970 few kidneys have been obtained from living nonrelated donors for transplantation.[20] Apparently there is a suspicion that people who want to donate a kidney to an unrelated person, perhaps even a stranger, are mentally unbalanced. Nevertheless, according to one poll, only 46% of those surveyed thought that there was less than an even chance that they would donate one of their kidneys to a stranger in need; only 24% definitely ruled it out.[21] Polls are notoriously unreliable, and there is often a conflict between what people say they would do and what they actually do. But such evidence suggests that living nonrelated donors need not be categorically excluded. Decisions about their acceptability should be made on a case-by-case basis.

The sale of organs. On occasion, the media present dramatic stories of people wanting to sell organs, such as kidneys and cornea, in order to raise money for themselves or for their families. The sale of organs has been reported in some countries, and it does not appear to be illegal in most states.[22] Earlier studies indicated that a policy of buying and selling blood is inefficient and increases risks for the recipient.[23] There may be good reasons to prohibit the sale of bodily parts. Many of these reasons concern justice, respect for persons, and the society's sense of itself. For example, it is sometimes argued that prohibition of the sale of organs is necessary to prevent exploitation in a society of great differences in the distribution of wealth. Serious abuses could be expected in a system of buying and selling organs, whether from one's own body or from cadavers.

Conclusions

The scarcity of organs for transplantion is not absolute. Each year enough people die under conditions that would permit the salvage of enough organs to meet the needs for transplantation. Utility would dictate changes in policies to obtain more organs, and such changes can be made without sacrificing other important moral principles such as justice and respect for persons.

First, there should be efforts to increase the supply of cadaveric organs, but living related and nonrelated donors, who are competent, informed, and acting voluntarily, should not be excluded in such areas as kidney donation. Second, a system of taking organs without regard for the wishes of the decedent and his/her family is ethically unacceptable as a violation of the principle of respect for persons. Third, the principles of justice and respect for persons require caution and perhaps even prohibition of the use of children and mentally retarded persons as "donors," even when they stand to gain nonmedical benefits. At the very least, strong procedural standards should be required. Fourth, there are good reasons to be suspicious of the sale of bodily organs and perhaps even to prohibit it altogether.

Concentrating on the most important source of organs-- cadavers-- I argued that a multifaceted approach is required. Whether we retain or modify the Uniform Anatomical Gift Act, more education of the public and medical professionals is essential, and improvements in organization are required. Public funds should be allocated for these measures. Even if the Uniform Anatomical Gift Act is morally preferable (ceteris paribus) because of its emphasis on voluntary giving, it is morally acceptable to change state laws to (a)require a decision for or against donation, or (b) presume consent for organ donation in the absence of a prior dissent or familial dissent. All three approaches-- the Uniform Anatomical Gift Act, requiring a decision, and presuming consent-- satisfy the criteria of justice and respect for persons. Which one should be adopted will thus depend on an assessment of utility.

Notes

1. Council on Scientific Affairs, "Organ Donor Recruitment," *Journal of the American Medical Association* 246 (Nov. 13, 1981): 2157.

2. Howard H. Kaufman, et al., "Kidney Donation: Needs and Possibilities," *Neurosurgery* 5 (1979): 237, 240; Frank P. Stuart, Frank J. Veith, and Ronald E. Cranford, "Brain Death Laws and Patterns of Consent to Remove Organs for Transplantation from Cadavers in the United States and 28 Other Countries," *Transplantation* 31 (1981): 239. It has also been noted that more than 80% of all decedents leave no wills.

3. Stuart, Veith, and Cranford, "Brain Death Laws...." p. 240.

4. These principles have been defended in Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (New York: Oxford University Press, first ed., 1979, second ed., 1983). See also the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Guidelines for the Protection of Human Subjects of Research*. DHEW Publication No. (OS) 78-0012 (1978), which emphasizes principles of beneficence (including nonmaleficence and utility), justice, and respect for persons.

5. Kaufman, et al., "Kidney Donation: Needs and Possibilities," p. 237.

6. Council on Scientific Affairs, "Organ Donor Recruitment," p. 2158; Kenneth J. Bart, et al., "Increasing the Supply of Cadaveric Kidneys for Transplantation," *Transplantation* 31 (1981): 383-87. Slightly different figures are given in the two papers.

7. Bart, et al., "Increasing the Supply of Cadaveric Kidneys for Transplantation," p. 385.

8. For some of the debate, see Paul Ramsey, *The Patient as Person* (New Haven: Yale University Press, 1970),chap.5, which argues that a policy of organized giving and receiving is better than a policy of taking, and James Muyskens "An Alternative Policy for Obtaining Cadaver Organs for Transplantation," *Philosophy and Public Affairs* 8 (1978): 88-99. There is also vigorous debate in the United Kingdom. See Ian Kennedy, "The Donation and Transplantation of Kidneys: Should the Law Be Changed?", Robert A. Sells, "Let's Not Opt Out: Kidney Donation and Transplantation," and Ian Kennedy, "Kidney Transplants: A Reply to Sells," *Journal of Medical Ethics* 5 (1979): 13-21 and 165-69; 6(1980): 29-32.

9. Stuart, Veith, and Cranford, "Brain Death Laws...." p. 238.

10. *Ibid.*, p. 239

11. *Ibid.*

12. *McFall* v. *Shimp*, Allegheny County Ct. Common Pleas, 10 Pa. D & C 3d 90. Excerpts appear in Michael H. Shapiro and Roy G. Spece, Jr., *Bioethics and Law: Cases, Materials and Problems* (St. Paul, Minn.: West Publishing Co., 1981), pp. 819-20.

13. See Kaufman, et al., "Kidney Donation: Needs and Possibilities," p. 238 (plus references). For some discussion of the issues, see R. L. Lawton, "Living Nonrelated Donors for Transplantation," *Proc. Dialysis Transplant Forum* (1978): 30-34; L. Kamstra-Hennen and R. G. Simmons, "Ethics of Related Donation: The Unsuccessful Case," *Proc. Dialysis Transplant Forum* (1978): 25-29; Carl H. Fellner and Shalmom H. Schwartz, "Altruism in Disrepute: Medical versus Public Attitudes toward the Living Organ Donor," *New England Journal of Medicine* 284 (March 18, 1971): 582-85.

14. Dorothy M. Bernstein, "The Organ Donor," *Journal of the American Medical Association* 237 (June 13, 1977): 2643.

15. *Ibid*.

16. Kaufman, et al., "Kidney Donation: Needs and Possibilities," p. 238.

17. Carl H. Fellner and John R. Marshall, "Kidney Donors: The Myth of Informed Consent," *Amer. J. Psychiat*. 126 (March 1970): 1245-51, and Robert M. Eisendrath, Ronald D. Guttmann, and Joseph E. Murray, "Psychologic Considerations in the Selection of Kidney Transplant Donors," *Surgery, Gynecology and Obstetrics* 129 (August 1969): 243-48.

18. Bernstein, "The Organ Donor," p. 2644.

19. For some of the issues, see Paul Ramsey, *The Patient as Person*; Norman Fost, "Children as Renal Donors," *New England Journal of Medicine* 296 (Feb. 17, 1977): 363-67; Norman K. Hollenberg, "Altruism and Coercion: Should Children Serve as Renal Donors?" *New England Journal of Medicine* 296 (Feb. 17, 1977): 390-91; John A. Robertson, "Organ Donations by Incompetents and the Substituted Judgment Doctrine," *Columbia Law Review* 76 (1976): 48-78; Dorothy M. Bernstein and Roberta G. Simmons, "The Adolescent Kidney Donor: The Right to Give," *Am. J. Psychiatry* 131 (December 1974): 1338-43.

20. "Live unrelated donors are generally not considered, although there is a minority opinion about this subject, even when children may be involved." Kaufman, et al., "Kidney Donation: Needs and Possibilities," p. 238, For a minority opinion, see Lawton, "Living Nonrelated Donors for Transplantation,"

21. Fellner and Schwartz, "Medical versus Public Attitudes toward the Living Donor," p. 583.

22. See Jim Brooke, "Kidney, Cornea Sale Flourishes in Brazil," *Washington Post* 10/12/81; Stuart, Veith, and Cranford, "Brain Death Laws...." p. 241; Shapiro and Spece, *Bioethics and Law*, pp. 823-28; Marvin Brams, "Transplantable Human Organs: Should Their Sale Be Authorized by State Statutes?" *American Journal of Law and Medicine* 3 (1977): 183-195; Clifton Perry, "Human Organs and the Open Market," *Ethics* 91 (October 1980): 63-71; and Ramsey, *The Patient as Person*. Ramsey opposes the sale of organs, while Brams and Perry argue for policies and laws authorizing such sales.

23. Richard Titmuss, *The Gift Relationship* (New York: Pantheon, 1971).

Mr. GORE. Thank you very much. I find your testimony really very helpful and thought provoking.

You two disagreed on the opting out system. In other words, we now have the system where you can choose to be an organ donor and if you don't make a choice, then it is assumed that you are not an organ donor.

There have been two proposals, among others. One is to set up a system that confronts everyone with the necessity of choosing yes or no without any coercion to make one choice or another, leaving aside the question of whether or not there is a subtle coercion attached to the forcing of the question.

I take it that both of you would think that system passes ethical muster. Is that correct? Dr. Veatch?

Dr. VEATCH. I am not sure the extent to which we disagree.

Mr. GORE. I am going to get to the other scenario after this one. This is the forcing of the choice. Dr. Childress went even further and endorsed an opting out system, but let me hold that one up.

Dr. VEATCH. I would favor forcing a response.

Mr. GORE. Forcing a response.

Dr. VEATCH. I think a yes-no forced choice may be more than people are prepared to make at this time. Yes, no and undecided would be satisfactory. I would like to see that on our income tax forms, or whatever we distribute regularly and store information in a computerized fashion.

Mr. GORE. We might have to investigate what effect that might have on tax evasion. [Laughter.]

Dr. Childress goes even further and says that in his view, it would be ethically permissible to assume that people would wish their organs donated absent an affirmative decision to say no.

You have a real problem with that, right, Dr. Veatch?

Dr. VEATCH. I think there are real problems with that. Again, I was attempting to summarize the positions taken by the major churches and major theologians working with the churches.

There has been historically a problem with the salvaging or opting out schemes. For example, we have a history, in some of the earlier cases, of organs being taken without familial or patient consent and then discovering only too late that there were family members available who would have objected. I think the opting out scheme creates an incentive for the system to fail to get donations recorded efficiently, seek out relatives when there is no indication of a donation.

I would prefer to maintain those incentives as long as possible to make the donation system work. Only if we discover that the donation system and the forced choice systems didn't do the job should we begin to consider ethics of the salvaging schemes. Quite frankly, I see serious problems in them.

Mr. GORE. Dr. Childress?

Dr. CHILDRESS. I think Professor Veatch is right. We probably don't disagree as much as it first appeared because we both agree on the ranking of the systems, with the Uniform Anatomical Gift Act at the top, as the preferable system; then a system of forced decision, and then a system of presumed consent.

Where we differ I think is in our assessment of how soon, if ever, we might need to move away from the Uniform Anatomical Gift

Act to one of the other systems. It may in part have to do with a judgment about need and a judgment about effectiveness.

I think we do perhaps disagree at one point, though. I understood Professor Veatch to suggest that the religious traditions have more unanimity or uniformity of disagreement with a policy of presumed consent than I think is actually the case.

I do not have a record of the opposition in the countries mentioned, but I think it is interesting to note that Israel is among the countries with a system of presumed consent, along with a number of other countries that pay a fair amount of attention to religious values.

It may well be that Professor Veatch is reflecting the individualism of most writers in the United States who work within theological contexts. It is the case that no English-speaking country, to my knowledge, has adopted presumed consent; this may reflect the tradition of individualism more than the religious traditions to which he referred.

Mr. GORE. We were unable to locate any data showing the success of organ donation in countries with presumed consent systems. You know of no such data, do you?

Dr. CHILDRESS. There is some information.

Mr. GORE. Would you provide that to the subcommittee? We have conducted a rather thorough search. There is some sketchy data, but we would like to have your thoughts on that as well.

Dr. CHILDRESS. It is not wholly adequate, but I would be glad to.

[The information follows:]

Without providing the statistics, one study notes that "countries with presumed consent seem to come closer to meeting their needs for transplant kidneys." (Frank P. Stuart, Frank J. Veith, and Ronald E. Cranford, "Brain Death Laws and Patterns of Consent to Remove Organs for Transplantation from Cadavers in the United States and 28 Other Countries," *Transplantation* 31 (1981): 239).

Mr. GORE. I will now recognize Congressman Reid.

Mr. REID. Mr. Chairman, I have no questions. Thank you.

Mr. GORE. Dr. Veatch, in this week's issue of the Journal of the American Medical Association you made some very interesting remarks.

One was, "If children are receiving or not receiving liver transplants because of funding allocation decisions, then that is the kind of insurance debate that the public ought to know about and participate in."

Could you elaborate on this for us?

Dr. VEATCH. I am concerned—and I think we have seen evidence of it in the Fiskes' comments—that rather subtle, behind the scenes judgments, either by government insurers or more often by private insurers, in effect determine whether or not a life-saving transplant takes place.

I would concur with Alex Capron in acknowledging that there are some services that simply cannot be included in insurance schemes, whether they be public or private. The decision to include or exclude it seems to me must meet two criteria:

First, it must meet the criteria of fairness. If some people are included, all people equally in need ought to be included as well.

Second, it has to meet what in the jargon of philosophy might be referred to as the criterion of publicity. The public needs to participate actively in the judgment. We need to ask ourselves as a society, do we want an insurance scheme that will cover liver transplants or kidney transplants. As a collectivity, we should understand that it is going to cost money for that insurance scheme if we cover those services, just the way dialysis costs the government money.

Mr. GORE. That is unclear in this case, however. We ought to eliminate the disagreements over that because the evidence indicates in some cases it is actually cheaper——

Dr. VEATCH. If it turns out to be cost effective to cover a medical service, then it is common sense. By every criterion you could imagine you would cover it.

The interesting cases are those where a service will be beneficial, often only marginally beneficially, add months to a life or add a year or two to life with suffering, perhaps, but at substantial cost.

For that kind of a question, it seems to me that, rather than insurance company bureaucrats or even those within the bowels of HHS making decisions about medicare-medicaid funding, the public as a whole needs to participate fully and actively and decide what gets covered. Once the decision is made, either everyone gets covered or no one gets covered.

Mr. GORE. Dr. Childress, you recommended a legal prohibition on the sale of organs and body parts. You don't think that there is a sufficient record of such practices to warrant legislative action at this time, do you?

Dr. CHILDRESS. I have no evidence to suggest that there is. I think in a way this would be a preemptive action to avoid some problems down the road, in part because of the increased publicity about the need for organs.

We have encountered some proposals for the sale of organs from philosophers and lawyers and others—sometimes not only tongue in cheek—and perhaps it would be wise to avoid some of the problems before they really become serious, again, in view of the increased publicity about the need for organs.

Mr. GORE. I understand the State of Georgia has already passed such a law. We will take that recommendation under consideration. I have found that my colleagues and I are becoming increasingly skeptical of preemptive laws. Your arguments are well put, and we will certainly take them under consideration when we go through our recommendations.

Let me thank the two of you for coming here. I always find the testimony of bioethicists fascinating and enlightening. I congratulate you on the work that you do. I have been convinced for some time, and even more so as chairman of this subcommittee, that the debate over bioethics is going to become a routine dialog in this country as new medical and biomedical techniques force choices upon us that are simply unfamiliar to us.

Our traditional legal and ethical systems don't equip us to make wise choices with respect to these new powers technology has conferred upon mankind. As a result, the relatively new discipline of bioethics has to scramble to keep up. We turn to it often for advice. We appreciate your pioneering work in this area.

Thank you very much.

The final panel will speak to us about the legal considerations involved in this area. We are pleased and honored to have Dr. David Wiecking, Office of the Chief Medical Examiner in Richmond, Va.; Dr. Roger Evans, research scientist with the Health and Population Study Center at the Battelle Institute in Seattle; and John McCabe, legal counsel with the National Conference of Commissioners on Uniform State Laws, from Chicago.

Dr. Wiecking, we will begin the panel with you. We are delighted to have you here. Without objection, the entire text of your remarks will be included in full in the record. We invite you to present that portion of it as you see fit. Welcome.

STATEMENTS OF DAVID WIECKING, M.D., OFFICE OF THE CHIEF MEDICAL EXAMINER, RICHMOND, VA.; DR. ROGER W. EVANS, RESEARCH SCIENTIST, HEALTH AND POPULATION STUDY CENTER, BATTELLE INSTITUTE, SEATTLE, WASH.; AND JOHN McCABE, LEGAL COUNSEL, NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS, CHICAGO, ILL.

Dr. **Wiecking**. Thank you, Mr. Chairman, gentlemen.

The medical examiners in this country are the physicians, many of them pathologists, who investigate violent, sudden, and unexpected deaths. Each year in this country there are about 25,000 homicide victims, 28,000 suicides, and 100,000 accidental deaths, 50,000 from automobile fatalities.

Many of these victims of sudden death are otherwise healthy young adults who would be excellent organ donors. Unfortunately, many of these organs are not utilized for that purpose. It would be an excellent idea if there were some system which would permit the orderly and expeditious use of transplantable organs from those victims.

The common law of dead bodies in the Anglo-American jurisdictions indicates that the dead body is the property of the next of kin for purposes of a decent disposition. Therefore, we must obtain permission from the next of kin for an organ harvest. The only significant change in this has been the Uniform Anatomical Gift Act, which has already been mentioned this morning.

Some States put donor forms on the back of the driver's license. In theory, it is a good idea. In practice, it often is not found until too late.

Another problem which occasionally occurs from the medical examiner's standpoint is that of releasing a donated organ from a medical examiner's case even with the express approval of the decedent or his next of kin.

Of course, from the medical-legal standpoint, it is important that the medical examiner be permitted to perform his statutory duty of determining the cause and manner of death without interference.

The usual problem, however, comes up where an organ is sought from a part of the body removed from the area of injury. This, in my opinion, should not present any insuperable problem to the medical examiner.

For instance, there is no reason, in my opinion, why a medical examiner should be reluctant to release a kidney for transplant from the body of a person who has been shot in the head. Occasionally, it is feared that some astute defense attorney will capitalize upon this. I don't think that is a viable objection.

Some States, as we have already heard, have enacted legislation which will permit the medical examiner to take organs from a case, presuming in law that the person has consented to the taking of the organs, subject to the express disapproval of the surviving next of kin; the opting in system, as I understand it.

This, obviously, would work to the increased number of organs, but it has been opposed by certain people from religious and libertarian viewpoints. I doubt that the majority of Americans would object to an opting in system, and I think it would be a very useful mechanism.

The only request from the medical examiner is that the medical examiner be notified promptly and without equivocation as to whether this person has or has not previously objected to the proposed taking of the organ.

Medical examiners in this country have jurisdiction over dead bodies pursuant, in the great majority of cases, to State law. The Federal Government has very limited jurisdiction over death and very few facilities to deal with it. How the Federal Government will affect the organ harvest situation is obviously the purpose of these hearings.

It would appear to me that it must come through encouragement to the States to change State jurisdictional statutes to give the medical examiners the power to obtain these organs when they are sought.

In my opinion, the vast majority—and I would hope all—of the medical examiners in this country cooperate with organ procurement programs and cooperate with transplant surgeons when they are requested. It does not mean increasing the number of autopsies. It does not mean changing the criteria for performance of a medical-legal autopsy. It means merely saving an otherwise discarded organ to be used to prolong the life of a living person.

The medical examiners in this country are ready to help. What we need is the statutory immunity and the statutory authority to do so.

Thank you.

Mr. GORE. Thank you very much.

[The prepared statement of Dr. Wiecking follows:]

STATEMENT OF DR. DAVID K. WIECKING, CHIEF MEDICAL EXAMINER FOR THE COMMONWEALTH OF VIRGINIA

I am Dr. David K. Wiecking of Richmond, Virginia. I am Chief Medical Examiner for the Commonwealth of Virginia and Chairman of the Board of Directors and immediate Past President of the National Assocation of Medical Examiners. The Medical Examiners in this country are the physicians, many of them pathologists, who perform the medico-legal investigations into violent and suspicious death cases. Each year in this country there are approximately 25,000 homicide victims, 28,000 suicides, and 100,000 accidental deaths, including about 50,000 automobile fatalities. Many of these victims of sudden death are otherwise healthy young adults who would be excellent organ donors for transplant purposes. Unfortunately however from the transplant surgeon's standpoint and even more importantly from the perspective of the patient awaiting the transplanted organ, very few of the transplantable organs from the suddent death victims can be utilized under the present state of the common and statutory law. It would be a tremendous benefit to the numbers and the success of transplant operations if the transplantable organs from the sudden death victims could be utilized in a systematic and expeditious method.

The common law of dead bodies in the Anglo-American jurisdictions indicates that the body of the deceased is the property of the next-of-kin for purposes of a decent disposition. The common law states that permission from the next-of-kin must be obtained in order for any portions of the dead body to be utilized for any other purpose. This notification and receipt of permission requirement causes frequent problems of time delay which render the sought-after organ useless for transplant. The only significant change in this common law requirement had been the introduction of state legislation of the Uniform Anatomical Gift Act, which gives the donor the power to direct diposition of his organs when he dies. The Uniform Anatomical Gift Act has been a significant help, but there are still many potential donors who have not completed donated forms, and others wherein the donation form is not discovered until too late. Some States have put the donor forms on the back of the driver's license, and while that again theoretically is a good idea it does not work too well in practice because too often the driver's license of the deceased is not examined or it is examined too late.

Another problem which occasionally occurs is the reluctance of the Coroner or Medical Examiner to release a donated organ even with the express approval of the decedent's next-of-kin. From the medico-legal standpoint, it is of course paramount that the Medical Examiner or Coronor be permitted to perform his principal medico-legal objective, which is the accurate and legally defensible determination of the cause and manner of death. Removal of an organ for transplant which interfers with the Medical Examiner's statutory duty is not appropriate. The usual situation however is that the Medical Examiner is concerned about the injured organs and the recovery of bullets and other items of evidence related to the death. The removal of a useful organ for transplant remote from the area of bodily injury and which does not impair the recovery of evidence from the body should not present an insuperable problem for the Medical Examiner. The transplant surgeon will not want an organ which has been injured, and the transplant surgeon can always attest to the normality of any organ which he has removed and transplanted. The occasionally voiced fear that an astute defense attorney will impeach the Medical Examiners' testimony because for example, the kidneys have been removed for transplant from a gunshot wound to the head case, is not a valid objection to the beneficial purposes of organ transplant.

Some States have enacted legislation permitting the Medical Examiner to take organs from the deceased upon the request of a transplant surgeon, presuming in law that the deceased and his family would approve, subject to express disapproval by the surviving kin. Such a statutory presumption certainly works to the increased efficiency of organ procurement and it probably represents the sentiments of the great majority of citizens. There are however opponents of such a presumption of approval, based on religious and libertarian viewpoints. It is a philosophical question which must be resolved in a rational manner for the betterment of our society as a whole. It is doubtful that the majority of Americans would object to the removal of a viable kidney from a suddenly deceased relative which can be used to prolong the life of another person. It would seem in the public interest to assume that such a donation is desirable and to put the burden of objecting to it upon the objector.

Medical Examiners and Coronors assume jurisdiction over dead bodies pursuant in the great majority of cases to state and local statutory law. The Federal government has very limited jurisdiction over sudden or violent death cases, and has very few facilities to deal with them on a routine basis. How the Federal government would implement procedures to expedite organ procurement from such cases is evidently the purpose of these hearings. It would seem that it must be done through encouragement to the States to enact enabling legislation to permit Medical Examiners and Coroners to obtain transplantable organs during the course of their routine statutorily authorized medico-legal autopsies. In my opinion the great majority of Medical Examiners and Coroners in this country would be cooperative with organ procurement and transplant operators provided they had the statutory immunity and authority to harvest the transplantable organs. It does not mean increasing the number of autopsies, nor changing the criteria for performance of a medico-legal autopsy, but merely the saving of an otherwise discarded organ to be used to prolong the life of a living person. The Medical Examiners of this country are ready to help; what they need is the statutory authority.

Mr. GORE. We would like to hear now from Dr. Roger Evans, the research scientist at the Health and Population Study Center at the Battelle Institute in Seattle. We appreciate your willingness to testify today instead of yesterday, Dr. Evans. Please proceed.

Dr. Evans. Thank you very much, Mr. Chairman.

I am very pleased to have the opportunity to testify. Under my direction at the Human Affairs Research Centers in Seattle, we are currently engaged in two major studies concerning organ transplantation. These are the national heart transplantation study and the national kidney dialysis and kidney transplantation study. Both studies are sponsored by the Health Care Financing Administration.

In developing a prototypical approach to the assessment of health care technology, the national heart transplantation study is addressing numerous issues we have discussed over the past 2 days.

These include the need for heart transplantation in the United States; the availability of donor hearts; the survival of heart transplant recipients; the cost of performing a heart transplant and providing the routine care required thereafter; the quality of life and rehabilitation enjoyed by heart transplant recipients; the legal and ethical issues pertaining to the selection of candidates, the procurement of organs, and the conduct of heart transplantation procedures.

The major objective of the study, once the foregoing analyses are completed, is to examine the impact of a potential coverage decision on the medicare program, transplant beneficiaries, and health care providers.

I might add that we could insert liver transplantation throughout. That is what I am trying to refer to by prototypical approach, that the issues that we are addressing in the heart transplant study are really generic to many health care technologies that have emerged today or have existed for some time.

For purposes of today's testimony, you are undoubtedly most interested in that component of the national heart transplantation study concerning donor organ procurement. First, let me describe each of several data collection efforts we plan to undertake. Having done this, I would then like to present some results from an informal inquiry we have just completed concerning the status of organ procurement with regard to the Uniform Anatomical Gift Act, brain death laws and organ retrieval procedures throughout the United States.

We have now planned and are about to carry out three separate data collection activities on both potential and actual donors. The first of these activities amounts to an analysis of existing data in an attempt to estimate the total number of people who die in hospitals each year who satisfy various donor selection criteria and thus are potential organ donors.

Eligible donors, as we have now heard, must be brain dead. It has been estimated that as many as 20,000 people die each year in the United States who have brain injury, tumor, or infarction, all of which may make them reasonable donor candidates.

To provide a more realistic estimate of the availability of donor hearts, we plan to modify the estimates derived through the above analyses based upon information we obtain in a second data collection effort; that being the potential organ donor survey.

You may be aware that in 1968 a Gallup poll indicated that 70 percent of Americans expressed their willingness to donate organs for transplantation at the time of their death. We heard yesterday and again today that the number has seemed to decline substantially since 1968 in the recent National Kidney Foundation poll. This may be a source of some concern, given the proceedings of this meeting.

In our survey, to be undertaken within the next several months, we plan to determine not only people's willingness to donate hearts, but also their willingness to donate kidneys, corneas, livers, lungs, pancreas, the skin, and bodies.

As you may be aware, people discriminate in terms of which organ they will donate. Some people are willing to donate kidneys but are unwilling to donate hearts and corneas, for example, so it is important to document each of these.

Data will also be obtained on age, sex, and various other social and demographic characteristics of the respondents. There are various characteristics that respondents have that exclude them as being potential donors, age being one of the foremost.

Respondents will be asked to answer questions regarding brain death and their willingness to permit organs to be removed from their spouse or children if, upon the declaration of brain death of the latter, they are found not to be carrying donor cards.

Finally, we plan to initiate an intense 12-month survey of nearly all organ procurement programs in the United States. The purpose of this survey is to determine how many actual kidney donors could have also been heart donors.

To better characterize the current state of organ procurement in the United States. I would like to take a few minutes to describe the results of a recent inquiry my associates and I have completed. We were interested in finding out some of the reasons for the continuing disparity between the supply and the demand for donor organs.

The interview guide we used focused on the following areas: State laws enacted, donor documentation, education and participation of public hospital personnel and law enforcement personnel, and consent required from decedent's next of kin.

Our inquiry found that all 50 States and the District of Columbia have adopted some form of the Uniform Anatomical Gift Act. We found that the majority of the larger organ procurement programs were well aware of the provisions of the act. However, some respondents were unaware of particular variations and a few were unaware of the provisions of the act. In addition, many people expressed misinterpretations of key provisions of the act.

DETERMINATION OF DEATH

We, specifically, asked people about their State statutes that delineate a definition of death. We found that although only 30 States have a legislatively determined definition of death, 48 used brain death as a standard for death in appropriate cases.

Whether legally stated or not, the decision to declare death is left to the physician, based on common law and the use of medically acceptable criteria. In these States, the medical community has set forth the criteria that gives structure, consistency, and confirmation to the determination of death.

The concept of brain death, at least in the medical profession, appears to be widely accepted. Thus, legislative recognition of the brain death standard does not appear to substantially affect the harvesting of organs for transplantation.

DOCUMENTATION

The documentation required to indicate a person's wish to donate his or her organs varies from State to State. Of primary interest were documents that potential donors might carry with them; namely, drivers' licenses and organ donor cards.

Forty-four States have a provision on their permanent drivers' licenses for organ donation. These provisions are optional, meaning that the driver has the option of stating his or her intentions regarding organ donation. A variety of methods are used to identify potential donors on licenses.

No State requires drivers to indicate whether or not they are willing to donate organs. This is contrary to what was stated yesterday. The State of Colorado, in checking with the attorney general's office, does not require a person check the yes or no box.

At best, drivers are presented with the option of stating their intentions. In Colorado, where the donor box appears on the face of the license, response has been impressive. Out of 1.5 million drivers, 900,000, that is 60 percent, are designated as donors.

Other States that place organ donation provisions on the faces of their drivers' licenses report fewer designated donors, between 1.5 percent and 8.5 percent. I believe that the discrepancy with regard to Colorado may be a result of misinterpretation. People simply feel they must check the box, although we can't be certain at this time.

Another document that may be used to identify potential donors is the organ donor card. These cards are generally distributed independently of the drivers' licenses by an organization within the State, such as the National Kidney Foundation or the Lion's Eye Bank. This form of documentation is available in all but three States.

Although the people we talked with could not provide exact figures, they repeatedly emphasized the fact that the percentage of donors with cards is very small. One transplant coordinator estimated that the number of card-carrying donors is 2 or 3 percent of all donors at most. Another person reported that out of 600 donors in the past 7 years, only 3 had carried donor cards.

If only such a small percentage of donors actually have cards, then what role do donor cards play? Leverage, said many people we talked to. When approaching the family, medical personnel and transplant coordinators use the card as evidence of the decedent's wish to donate his or her organs. It is also used as an educational tool, a symbol to promote awareness and discussion of organ donation, especially among families.

When asked how it is determined if a potential organ donor is carrying a card, we found no State had a comprehensive procedure to be followed by law enforcement and medical personnel who might be involved with accident victims. Only one State reported that its State police department had an official policy directing its force to look for donor cards at the scene of accident and to alert hospital personnel if one was found.

When we asked what action medical personnel would take to identify a potential donor, the people we talked to gave a variety of responses. The organ-procurement agencies in a few States have established ties with at least one intensive care unit nurse in almost every hospital who acts as an organ retrieval coordinator. The nurse/coordinator monitors the course of every patient in the unit. When a patient's condition is clearly terminal, the nurse arranges with the attending physician to have one of them talk with the family about organ donation, after the family has been informed of their relative's prognosis. With this system, almost every potential donor is identified and his or her family approached concerning organ donation.

Consent. Perhaps the most crucial step in the entire organ donation procedure is obtaining consent from the next of kin. If donor documents are not available—and the percentage of donors with cards is negligible—the Uniform Act authorizes survivors to make anatomical gifts of all or part of the decedent's body, unless they are aware of contrary intentions by the decedent.

The first consent question we asked was, "If a card is not found, would next of kin be consulted concerning organ donation?" People we talked to in 45 States answered yes. This may be the case in four other States, but not necessarily. Transplant coordinators explained that it depends strictly on the attending physician. In the remaining two States, the issue of organ donation is never raised with survivors because there are no organ procurement programs in the States.

We also asked who approached the decedent's family concerning anatomical gifts. In some institutions, this responsibility lies with one person or department exclusively. Generally speaking, however, the people we talked to named more than one source.

Section 2(e) of the Uniform Anatomical Gift Act states, "The rights of the donee created by the gift are paramount to the rights of others except as provided by Section 7(d) (medical examiners' duties)." Given proper documentation, such as a signed donor card or marked driver's license, physicians may legally remove organs from decedents even if families object. The results of our inquiry, however, indicate that this rarely happens.

With donor documentation available, family consent is still required in the vast majority of States. People we talked to in 47 States said that surgeons require family approval. When presented with the hypothetical situation in which the decedent's relatives could not be located, only 11 of the 47 States said they would probably proceed with organ removal.

Three major reasons were given for requiring family consent despite valid donor documentation. In 28 States, people said they rely on family confirmation in order to avoid potential legal disputes.

Ethical considerations are another major reason that next of kin consent is required. It is a factor in 25 States where medical personnel feel that it is morally wrong to ignore objections raised by survivors.

Finally, 15 States cited fear of bad publicity as a reason for obtaining family consent for organ removal.

Only four States take full advantage of the provisions of their anatomical gift acts. Transplant coordinators in these states explained that potential donor intentions, legally documented, cannot be vetoed by others. The family is simply informed of the procedure as a matter of formality. The results of the inquiry reported here suggest several areas which should be further addressed in the future.

Clearly there are a number of important issues concerning the impact of laws pertaining to anatomical gifts. It is evident that the original goal of the measure has not been achieved; that is, the Uniform Anatomical Gift Act alone has not succeeded in more closely matching supply to demand. Anatomical gift laws have been enacted, brain death laws passed, documents distributed and medical personnel educated, but the demand still far exceeds the supply.

There is little doubt that a greater number of signed donor cards would be likely to increase the supply of donor organs. Transplant coordinators across the country emphasized that very few families withhold consent when made aware of the decedent's donor documentation.

The fact that only a small percentage of donors actually have donor cards raises questions about current methods of document distribution. The work of private groups or institutions is limited by their own resources and, at best, they can only ask the people they reach to consider their cause.

There are certainly things that can be done to increase card distribution, such as making cards available in more hospitals, doctors' offices and schools, but these efforts cannot reach all groups or individuals in the public sector. In contrast, the government not only has the greatest access to the public, but also has the capability of devoting substantial monetary resources to the task of promoting organ donation.

Should the government play a more aggressive role in promoting organ donation? Should it assume the responsibility of at least presenting the issue to every adult. Every state could do more to insure that the organ donor section on the driver's license is more than a box that one probably ignores or forgets to fill in.

People we talked to indicated that the greatest difference among programs and hospitals is not in how they identify donors but rather how consistently they attempt to do it. Building a network of involved, motivated referral sources among medical personnel requires a great deal of effort, patience and farsightedness on the part of organ procurement agencies.

The results of our inquiry also suggest that the Uniform Act is largely ignored when it comes to matters of consent. Although the Act recognizes donor documents as sufficient evidence of the decedent's intentions and even extends blanket protection to physicians who remove organs while acting in good faith, the vast majority of medical institutions in this country will not allow organ removal without consent from the next of kin.

Thus, while the philosophy of the act is to carry out the decedent's wish, the reality is that these wishes cannot be carried out until the family approves. Most institutions base this policy on their fear of prosecution, a definite sign that they feel the protection offered them in the Uniform Act is not sufficient.

Legislation may or may not remove all perceived barriers to effective organ procurement. There remains the question of how to deal with ethical objections and the fear of bad publicity. Again, an important key to the answer is education, both professional and public. Organ donation must be presented in a positive light. If the attitudes of medical personnel and the general public reflected these positive aspects of organ donation, ethical objections and the fear of legal liability and bad publicity would not be seen as such serious obstacles.

I would like to conclude my testimony with some comments on the National Kidney Dialysis and Kidney Transplantation Study. This study is concerned with the costs and benefits associated with various approaches to the treatment of kidney failure, often referred to as end-stage renal disease. The purpose of the study is to identify which of several treatment modalities is least costly to the Federal Government yet, at the same time, is most beneficial to the patients being treated.

I think, at the outset, that we would all agree that cost should not be the sole criterion upon which we base our judgment of the effectiveness of alternative treatments. Yet, at the same time, we recognize that cost is a very important consideration. This has been emphasized repeatedly over the past 2 days.

It is in this regard that kidney dialysis and transplantation raise some very difficult questions which we must confront as a society. As we now see, these questions have to do with what we might call resource allocation and rationing.

I have thoroughly considered these issues in two papers which will appear in the April 15 and April 22 issues of the Journal of the American Medical Association. That paper is part of my written testimony.

In my estimation, we have now reached a point where there is what I might call a new medical imperative, that being to develop policies and procedures for making resource allocation and rationing decisions. These decisions, I might add, cannot be left solely to physicians; that is, it requires a great deal of involvement on behalf of governmental agencies and personnel.

In 1982 it cost approximately $1.8 billion to treat about 65,000 patients with kidney failure in the United States. This is up from $747 million in 1978. While the actual cost per patient per year for treating end-stage renal disease has decreased when adjusted for the rate of inflation, rising total program costs have led to a reconsideration of the future viability of the end-stage renal disease program.

Policymakers are also concerned that the outcomes experienced by many patients are unsatisfactory, thus raising questions about the overall benefits of the program as well.

A most difficult question is now being asked. Are ESRD patients—that is, people who have kidney failure—truly benefiting from long-term maintenance dialysis and kidney transplantation?

Recently, several studies have shown that the benefits derived by many patients are relatively few. Indeed, many patients appear to lead unacceptable lives, characterized by frequent hospitalization, family discord, and personal catastrophe. Thus, while it cannot be denied that the ESRD program has saved lives of patients with chronic renal failure, attention is now beginning to focus on the quality of their lives.

In the National Kidney Dialysis and Kidney Transplantation Study, the quality of life of 859 patients randomly selected from 11 dialysis and transplant centers across the United States, has been assessed. These results show clearly that kidney transplantation, when successful, is a superior treatment alternative to long-term maintenance dialysis of any kind.

At the same time, however, it is evident from our results that patients who have experienced a failed kidney transplant have significant medical and rehabilitation problems which distinguish them from successful kidney transplant recipients.

Thus, rather than use the results of this study to promote kidney transplantation as optimal treatment modality for end-stage renal disease, I remain committed to the position that dialysis and transplantation must be viewed as complementary, rather than competitive treatment modalities.

Over the past 2 days there has been considerable discussion of the cost of organ transplantation. Moreover, I would like to underscore the fact that the cost of dying with untreated catastrophic disease is far less than providing even routine treatment for catastrophic disease; that is, if no attempt is made to reverse the disease process upon the diagnosis of a condition, such as biliary atresia or idiopathic cardiomyopathy, dollars are in a sense saved. This was pointed out yesterday by Dr. Starzl, when he was citing the study which indicated that the cost of dying was quite expensive.

As a society, we obviously find it cruel to withhold even routine treatment. This has been borne out over the past 2 days. Thus, the cost of a transplant procedure must be viewed as the marginal added costs which are incurred over and above the routine medical care that would have been provided regardless of whether or not the patient in question received a transplant.

For example, a patient who does not receive a transplant will incur considerable medical expenses, regardless of whether or not they receive a transplant. We need to keep this in mind when we consider cost. Despite this, however, we must recognize that there are truly limits to how much we can realistically do to spare human lives from that which is truly inevitable: death.

For example, is it a wise use of scarce resources to do everything imaginable to maintain the life of a patient with a terminal cancer whose prospects of living beyond a few months is virtually nil? Are these resources not better spent in providing care to other patients who are likely to benefit?

At the same time, we find it especially cruel when representatives of major government insurance companies, such as medicare, medicaid, and CHAMPUS, as well as private insurance companies, such as Blue Cross and Blue Shield decide not to pay for procedures such as heart and liver transplantation.

Yet, what we often fail to recognize is that these coverage determinations, as I refer to them, are by no means simple. A considerable amount of data must be amassed and analyzed to better understand the implications—financial, legal, ethical, and sociomedical—of the decisions we make. This is precisely what we are doing for the Federal Government in the Health Care Financing Administration-sponsored National Heart Transplantation Study.

Is it not unusual that at at time when we are considering the possibility that the medicare program is likely to go broke we are suggesting that coverage be extended to include very expensive lifesaving therapy, such as liver transplantation, which is estimated to cost between $175,000 to $200,000 per procedure?

Is it not time that we begin to ask how many of these procedures can be supported by public funds? I think the ethicists have made this point.

With these remarks I do not intend to suggest that many of the costly procedures we have discussed over the past 2 days are not worthy of support. Indeed, they are. What I want to suggest is that perhaps resource allocations to public health care programs do not reflect the priority that the public attaches to them.

In effect, if the public only wants the finest health care available, as was suggested yesterday, is it truly willing to pay for it? Do current allocations to publicly subsidized health care programs reflect this public commitment? In effect, should more resources be allocated to health care programs and less to alternative uses?

Ultimately we must recognize that the Brandon Halls and the Jamie Fiskes really serve to epitomize a much larger problem we must confront as a society. It clearly goes well beyond the organ procurement problem itself.

There are many people in this world with a variety of medical problems which can be treated if we are willing to expend the required resources, but since the necessary resources are truly finite, we must make what some have referred to as tragic choices.

It is in making these decisions that we come to recognize that illness, despite its tragedy, is part of the human condition, and that illness provides meeting and insight into the human condition.

Thank you.

[The prepared statement of Mr. Evans follows:]

ORAL TESTIMONY

Presented before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

of the

COMMITTEE ON

SCIENCE AND TECHNOLOGY

U. S. HOUSE OF REPRESENTATIVES

on

April 14, 1983

by

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Mr. Chairman and Members of the Subcommittee:

As a Research Scientist at the Battelle Human Affairs Research Centers located in Seattle, Washington, I am pleased to testify today. Under my direction, the Human Affairs Research Centers is currently engaged in two major studies concerning organ transplantation. These are: the National Heart Transplantation Study and the National Kidney Dialysis and Kidney Transplantation Study. Both studies are sponsored by the Health Care Financing Administration (HCFA).

In developing a prototypical approach to the assessment of health care technology, the National Heart Transplantation Study is addressing numerous issues including: the need for heart transplantation in the U.S., the availability of donor hearts, the survival of heart transplant recipients, the cost of performing a heart transplant and providing the routine care required thereafter, the quality of life and rehabilitation enjoyed by heart transplant recipients, the legal and ethical issues pertaining to the selection of candidates, the procurement of organs, and the conduct of heart transplantation procedures. The major objective of the study, once the foregoing analyses are completed, is to examine the impact of a potential coverage decision on the Medicare program, transplant beneficiaries, and health care providers.

For purposes of today's testimony, you are undoubtedly most interested in that component of the National Heart Transplantation Study concerning donor organ procurement. First let me describe each of several data collection efforts we plan to undertake. Having done this, I would then like to present some results from an informal inquiry we have just completed concerning the current status of organ procurement with regard to the Uniform Anatomical Gift Act, brain death laws, and organ retrieval procedures throughout the United States.

We have now planned and are about to carry out three separate data collection and data analysis activities on both potential and actual organ donors. The first of these activities amounts to an analysis of existing data in an attempt to estimate the total number of people who die in hospitals each year and who satisfy various donor selection criteria and, thus, are potential organ donors. Eligible donors must be brain-dead. It has been estimated that as many as 20,000 people die each year in the U.S. who have brain injury, tumor, or infarction, all of which may make them reasonable donor-candidates (Council on Scientific Affairs, 1981:2157).

To provide a more realistic estimate of the availability of donor hearts, we plan to modify the estimates derived through the above analyses based upon information we obtain in a second data collection effort, that being, the Potential Organ Donor Survey. You may be aware that in 1968 a Gallup poll indicated that 70.0 percent of Americans expressed their willingness to donate organs for transplantation at the time of their death (Council on Scientific Affairs, 1981). In our survey, to be undertaken within the next several months, we plan to determine not only people's willingness to donate hearts, but also their willingness to donate kidneys, corneas, livers, lungs, pancreases, skin, and bodies. Data will also be obtained on age, sex, and various other social and demographic characteristics of the respondents. Finally, respondents will be asked to answer questions regarding brain death and their willingness to permit organs to be removed from their spouse or children if, upon the declaration of brain death of the latter, they are found not to be carrying donor cards.

Finally, we plan to initiate an intense 12-month survey of nearly all organ procurement programs in the U.S. The purpose of this survey is to determine how many actual kidney donors could also have been heart donors.

Now, to better characterize the current state of organ procurement in the U.S., I would like to take a few minutes to describe the results of a recent informal inquiry my associates and I have completed. We are interested in finding out some of the reasons for the continuing disparity between the supply of, and demand for, donor organs. The interview guide we used focused on the following areas:

- state laws enacted;
- donor documentation;
- education and participation of public, hospital personnel, and law enforcement personnel;
- consent required from decedent's next-of-kin.

In our inquiry we found that all 50 states and the District of Columbia have adopted some form of the Uniform Anatomical Gift Act. We found that the majority of the larger organ procurement programs were well aware of the provisions of the Act, however some respondents were unaware of particular variations and a few were unaware of the provisions of the Act. In addition, many people expressed misinterpretations of key provisions of the Act.

Determination of Death

We specifically asked people about their state's statutes that delineate a definition of death. We found that although only 30 states have a legislatively determined definition of death, 48 (94%) use brain death as a standard for death in appropriate cases.[1] Whether legally stated or not, the decision to declare death is left to the physician, based on common law and the use of medically acceptable criteria. In these states, the medical community has set the criteria that give structure, consistency, and confirmation to the determination of death. The concept of brain death, at least in the medical profession, appears to be widely accepted and, thus, legislative recognition of the brain death standard does not appear to substantially affect the harvesting of organs for transplantation.

Documentation

The documentation required to indicate a person's wish to donate his or her organs varies from state to state. Of primary interest were documents that potential donors might carry with them, namely drivers' licenses and organ donor cards.

Forty-four states[2] (86%) have a provision on their permanent drivers' licenses for organ donation. These provisions are optional, meaning that the driver has the option of stating his or her intentions regarding organ donation. A variety of methods are used to identify potential donors on licenses:

No state requires drivers to indicate whether or not they want to donate organs. At best, drivers are presented with the option of stating their intentions. In one state[3] where the donor box appears on the face of the license, response has been impressive: out of 1.5 million drivers, 900,000 (60%) are designated as donors. Other states[4] that place organ donation provisions on the faces of their driver's licenses report fewer designated donors, between 1.5% and 8.5%.

Another document that may be used to identify potential donors is the organ donor card. These cards are generally distributed independently of the drivers' licenses by an organization within the state, such as the National Kidney Foundation or the Lion's Eye Bank. This form of documentation is available in all but three states.[5]

Although the people we talked with could not provide exact figures, they repeatedly emphasized the fact that the percentage of donors with cards is very small. One transplant coordinator estimated that the number of card-carrying donors is two or three percent of all donors at most. Another person reported that out of 600 donors in the past seven years, only three had carried donor cards.

If only such a small percentage of donors actually have cards, then what role do donor cards play? Leverage, said many people we talked to. When approaching the family, medical personnel and transplant coordinators use the card as evidence of the decedent's wish to donate his or her organs. It is also used as an educational tool, a symbol to promote awareness and discussion of organ donation, especially among families.

Procedures

When asked how it is determined if a potential organ donor is carrying a card, we found no state had a comprehensive procedure to be followed by law enforcement and medical personnel who might be involved with accident victims. Only one state[6] reported that its state police department had an official policy directing its force to look for donor cards at the scene of an accident and to alert hospital personnel if one was found.

When we asked what action medical personnel would take to identify a potential donor, the people we talked to gave a variety of responses. The organ procurement agencies in a few states have established ties with at least one intensive care unit nurse in almost every hospital who acts as an organ retrieval coordinator. The nurse/coordinator monitors the course of every patient in the unit. When a patient's condition is clearly terminal the nurse arranges with the attending physician to have one of them talk with the family about organ donation--after the family has been informed of their relative's prognosis.

Consent

Perhaps the most crucial step in the entire organ donation procedure is obtaining consent from the next-of-kin. If donor documents are not available, the Uniform Act authorizes survivors to make anatomical gifts of all or part of the decedent's body, unless they are aware of contrary intentions by the decedent. The first consent question we asked was, "If a card is not found, would next-of-kin be consulted concerning organ donation?" People we talked to in 45 states (88%) answered yes. This may be the case in four other states,[7] but not necessarily; transplant coordinators explained that it depends strictly on the attending physician. In the remaining two states,[8] the issue of organ donation is never raised with survivors because there are no organ procurement programs in the states.

We also asked who approached the decedent's family concerning anatomical gifts. In some institutions, this responsibility lies with one person or department exclusively. Generally speaking, however, the people we talked to named more than one source.

Section 2E of the Uniform Anatomical Gift Act states, "The rights of the donee created by the gift are paramount to the rights of others except as provided by Section 7(d) (medical examiners' duties)." Given proper documentation, such as a signed donor card or marked driver's license, physicians may legally remove organs from decedents even if families object. The results of our inquiry, however, indicate that this rarely happens. With donor documentation available, family consent is still required in the vast majority of states. People we talked to in 47 states[9] (92%) said that surgeons require family approval. When presented with the hypothetical situation in which the decedent's relatives could not be located, only 11 of the 47 states[10] said they would probably proceed with organ removal.

Three major reasons were given for requiring family consent despite valid donor documentation. In 28 states (55%), people said they rely on family confirmation in order to avoid potential legal disputes. Ethical considerations are another major reason that next-of-kin consent is required. It is a factor in 25 states (49%) where medical personnel feel that it is morally wrong to ignore objections raised by survivors. Finally, 15 states (29%) cited fear of bad publicity as a reason for obtaining family consent for organ removal.

Only four states (8%) take full advantage of the provisions of their anatomical gift acts. Transplant coordinators in these states explained that potential donors' intentions--legally documented--cannot be vetoed by others. The family is simply informed of the procedure as a matter of formality.

The results of the inquiry reported here, however, suggest several areas which should be further addressed in the future (Oksa and Pasternack, 1981; van der Vleit and Koostra, 1982; van der Vleit et al., 1982; Barnes, 1983).

Clearly there are a number of important issues concerning the impact of laws pertaining to anatomical gifts. It is evident that the original goal of the measure has not been achieved; that is, the Uniform Anatomical Gift Act alone has not succeeded in more closely matching supply to demand.

There is little doubt that a greater number of signed donor cards would be likely to increase the supply of donor organs--transplant coordinators across the country emphasized that very few families withhold consent when made aware of the decedent's donor documentation. The fact that only a small percentage of donors actually have donor cards raises questions about current methods of document distribution. The work of private groups or institutions is limited. There are certainly things that can be done to increase card distribution, such as making cards available in more hospitals, doctors' offices and schools, but these efforts cannot reach all groups or individuals in the public sector. In contrast, the government not only has the greatest access to the public, but also has the capability of devoting substantial monetary resources to the task of promoting organ donation.

Should the government play a more aggressive role in promoting organ donation? Should it assume the responsibility of at least presenting the issue to every adult? Every state could do more to ensure that the organ donor section on the driver's license is more than a box that one probably ignores or forgets to fill in.

People we talked to indicated that the greatest difference among programs and hospitals is not in how they identify donors but rather in how consistently they attempt to do it. Building a network of involved, motivated referral sources among medical personnel requires a great deal of effort, patience, and farsightedness on the part of organ procurement agencies.

The results of our inquiry also suggest that the Uniform Act is largely ignored when it comes to matters of consent. Although the Act recognizes donor documents as sufficient evidence of the decedent's intentions and even extends blanket protection to physicians who remove organs while "acting in good faith," the vast majority of medical institutions in this country will not allow organ removal without consent from the next-of-kin.

Most institutions base this policy on their fear of prosecution, a definite sign that they feel the protection offered them in the Uniform Act is not sufficient.

Legislation may or may not remove all perceived barriers to effective organ procurement. There remains the question of how to deal with ethical objections and the fear of bad publicity. Again, an important key to the answer is education, both professional and public. Organ donation must be presented in a positive light. If the attitudes of medical personnel and the general public reflected the positive aspects of organ donation, ethical objections and the fear of legal liability and bad publicity would not be seen as such serious obstacles.

I would like to conclude my testimony with some comments on the National Kidney Dialysis and Kidney Transplantation Study. This study is concerned with the costs and benefits associated with various approaches to the treatment of kidney failure. The purpose of the study is to identify which of several treatment modalities is (are) least costly to the federal government yet, at the same time, is (are) most beneficial to the patients being treated. I think, at the outset, that we would all agree that cost should not be the sole criterion upon which we base our judgment of the effectiveness of alternative treatments. Yet, at the same time, we recognize that cost is a very important consideration.

It is in this regard that kidney dialysis and transplantation raise some very difficult questions which we must confront as a society. These questions have to do with resource allocation and rationing. I have thoroughly considered these issues in two papers which will appear in the April 15, 1983 and April 22, 1983 issues of the Journal of the American Medical Association. In my estimation, we have now reached a point where there is what I might call a "new medical imperative," that being to develop policies and procedures for making resource allocation and rationing decisions.

In 1982 it cost approximately $1.8 billion to treat about 65,000 ESRD patients in the U.S. (Iglehart, 1982a; 1982b). This is up from $747.2 million in 1978. While the actual cost per patient per year for treating ESRD has decreased (when adjusted for the rate of inflation) (Lowrie and Hampers, 1981; 1982; Rettig, 1980a; 1980b), rising total program costs have led to a reconsideration of the future viability of the ESRD Program.

Policymakers are also concerned that the outcomes experienced by many patients are unsatisfactory, thus raising questions about the overall benefits of the program as well. A most difficult question is now being asked: are ESRD patients truly benefiting from long-term maintenance dialysis and kidney transplantation? Recently, several studies have shown that the benefits derived by many patients are relatively few (Gutman and Amara, 1978; Gutman et al., 1981; Rennie, 1981; Tews et al., 1980; Poznanski et al., 1978). Indeed, many ESRD patients appear to lead unacceptable lives characterized by frequent hospitalization, family discord, and personal catastrophe. Thus, while it cannot be denied that the ESRD Program has saved lives of patients with chronic renal failure, attention is now beginning to focus on the quality of their lives (Editorial, 1980; Editorial, 1981; Caplan, 1981).

In the National Kidney Dialysis and Kidney Transplantation Study, the quality of life of 859 patients randomly selected from eleven dialysis and transplant centers across the United States has been assessed. These results show clearly that kidney transplantation, when successful, is a superior treatment alternative to long-term maintenance dialysis of any kind. At the same time, however, it is evident from our results that patients who have experienced a failed kidney transplant have significant medical and rehabilitation problems which distinguish them from successful kidney transplant recipients. Thus, rather than use the results of our study to promote kidney transplantation as the optimal treatment modality for end-stage renal disease, I remain committed to the position that dialysis and transplantation must be viewed as complementary rather than competitive treatment modalities.

Over the past two days there has been some discussion of the cost of organ transplantation. I would like to underscore the fact that the cost of dying with untreated catastrophic disease is far less than providing even routine treatment for a catastrophic disease. That is, if no attempt is made to reverse the disease process upon the diagnosis of a condition such as idiopathic cardiomyopathy or biliary atresia, dollars are saved. Yet, as a society we obviously find it cruel to withhold even routine treatment. Thus, the cost of a transplant procedure must be viewed as the marginal additional costs which are incurred over and above routine medical care that would have been provided regardless of whether or not the patient in question received a transplant. For example, a patient who does not receive a transplant will incur considerable medical expenses regardless of whether or not they receive a transplant.

Despite this, however, we must recognize that there are truly limits to how much we can realistically do to spare human lives from that which is truly inevitable--death. For example, is it a wise use of scarce resources to do everything imaginable to maintain the life of a patient with terminal cancer whose prospects of living beyond a few months is virtually nil? Are these resources not better spent in providing care to other patients who are likely to benefit?

At the same time we find it is especially cruel when representatives of major government insurance programs such as Medicare, Medicaid, and CHAMPUS as well as private insurance companies decide not to pay for procedures such as heart and liver transplantation. Yet, what we often fail to recognize is that these coverage determinations, as I refer to them, are by no means simple. A considerable amount of data much be amassed and analyzed to better understand the implications--financial, legal, ethical, and sociomedical--of the decisions we make. This is precisely what we are doing for the Federal government in the HCFA-sponsored National Heart Transplantation Study. Is it not unusual that at a time when we are considering the possibility that the Medicare program is likely to go broke, we are suggesting that coverage be expanded to include very expensive life-saving therapies such as liver transplantation which is estimated to cost between $175,000 - $200,000 per procedure? Is it not time that we begin to ask, how many of these procedures can be supported by public funds?

With these remarks I do not intend to suggest that many of the costly procedures we have discussed over the past two days are not worthy of support. Indeed they are. What I want to suggest is that perhaps resource allocations to public health care programs do not reflect the priority that the public attaches to them. In effect, if the public wants only the finest health care available, as was suggested yesterday, is it truly willing to pay for it? And, do current allocations to publicly subsidized health care programs reflect this public commitment? In effect, should more resources be allocated to health care programs and less to alternative uses?

Ultimately we must recognize that the Brandon Hall's and the Jamie Fiske's really serve to epitomize a much larger problem we must confront as a society. There are many people in this world with a variety of medical problems which can be treated if we are willing to expend the required resources. But, since the necessary resources are truly finite, we must make what some have referred to as "tragic choices." It is in making these decisions that we come to recognize that illness, despite its tragedy, is part of the human condition and that illness provides meaning and insight into the human condition.

FOOTNOTES

1. All states and the District of Columbia, except: Illinois, Massachusetts, Utah

2. All states and the District of Columbia except: Delaware, Florida, Hawaii, Nebraska, Nevada, Pennsylvania, Washington

3. Colorado

4. Minnesota, Connecticut, Alabama, North Carolina

5. Michigan, North Dakota, Wyoming

6. Louisiana

7. Arizona, Illinois, Kansas, Mississippi

8. Montana, Kentucky

9. Alabama, Alaska, Arkansas, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Indiana, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Mississippi, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin

10. District of Columbia, Georgia, Kentucky, Maryland, Massachusetts, Missouri, Nevada, New Hampshire, North Carolina, Oregon, Virginia

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APPENDIX A

THE NATIONAL HEART TRANSPLANTATION STUDY: AN OVERVIEW

The National Heart Transplantation Study: An Overview*

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An announcement appeared in the January 22, 1981, issue of the *Federal Register* asking hospitals and medical centers to participate in a study of heart transplantation, now the National Heart Transplantation Study.[1] The announcement was made by the Health Care Financing Administration (HCFA), the federal agency that is responsible for administering Medicare, Medicaid, and other programs for the well-being of the nation's aged, poor, and disabled.[2] In its role as administrator of these programs, the HCFA must make two types of policy decisions: (1) whether or not an item or service is eligible for payment under one of the foregoing programs, and (2) how much to pay for a covered item or service.

Any emerging, new, or existing health care technology, whether a procedure, device, or drug, is of obvious concern to the Health Care Financing Administration since it must decide how federal funds will be used to pay for medical expenses incurred by beneficiaries under the programs it administers.

The need for a study on heart transplantation became apparent when questions raised by then Secretary of the Department of Health and Human Services, Patricia Roberts Harris, about the procedure could not be answered satisfactorily. In fact, an ad hoc panel of 18 cardiologists and cardiac and transplant surgeons assembled by the National Heart, Lung, and Blood Institute (NHLBI) at the request of the National Center for Health Care Technology concluded that it could make no "generalized or unqualified statement" about the safety, efficacy, and reasonableness of heart transplantation.[3]

Background

In November 1979, the Health Care Financing Administration first authorized payments for heart transplantation procedures performed for Medicare beneficiaries at Stanford University Medical Center. This was an interim decision based on preliminary findings by the Public Health Service regarding the safety and efficacy of heart transplants performed at that center. When reimbursement was tentatively authorized, HCFA anticipated that it would soon be able to reach a final decision not only about coverage at Stanford, but also on generally applicable criteria for approving Medicare coverage of heart transplantation at other facilities.

As HCFA proceeded to review Medicare coverage of heart transplants, it decided that the issues were much more complex than originally thought and could not be immediately resolved because the data were inadequate. There were numerous questions, for example, on the patient-selection process, the basis for assessing safety and efficacy, the long-term social and economic consequences of the procedure, broad ethical considerations, the cost-effectiveness of the procedure, and the potential, if any, for substantial expansion in the availability of heart transplants. It was concluded that HCFA did not have sufficient information at that time to develop generally applicable coverage criteria.

The National Heart Transplantation Study

On June 12, 1980, Secretary Harris announced the decision to exclude heart transplants from Medicare coverage with the exception of a few patients who had previously been selected for and were awaiting transplants. This announce-

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ment was published in the *Federal Register* on August 6, 1980.[4] At the same time, Mrs. Harris announced that all new health technologies must be evaluated not only for their medical efficacy but also for their social consequences before "financing their wide distribution."[3]

The decision to exclude heart transplants from Medicare coverage was accompanied by an announcement that the HCFA, in close cooperation with the Public Health Services' National Center for Health Care Technology (NCHCT), would conduct a study of the sort described by Mrs. Harris. The National Heart Transplantation Study was to address numerous issues, including: need for heart transplantation in the U.S., availability of donor hearts, survival of heart transplant recipients, cost of performing a heart transplant and the routine care required thereafter, quality of life and level of rehabilitation enjoyed by heart transplant recipients, and legal and ethical issues pertaining to the selection of candidates for heart transplantation. The major objective of the study, once the foregoing analyses were completed, would be to examine the impact of potential coverage decisions on beneficiaries, the Medicare program, and the health care providers.

Selection of Institutions to Participate in the Study

Six institutions were selected to serve as clinical centers for the study: Stanford University Medical Center, Medical College of Virginia, University of Arizona Health Sciences Center, University of Minnesota, University of Pittsburgh, and Columbia Presbyterian Medical Center. Although other institutions applied, it was decided to limit the participation to only six. It had been decided beforehand that cardiac transplantation could not be considered as simply a surgical procedure. It was also decided that clinical effectiveness and usefulness depend upon careful and appropriate patient selection, expert surgery and postoperative care, adequate immunosuppression protocols, availability of methods for immunologic monitoring and treating rejection, thorough procedures for patient education, and established protocols for liaison with the patient's own physicians for subsequent lifelong care.

Criteria for selecting participating clinical centers were developed by the National Heart, Lung, and Blood Institute, with the advice of an advisory group of experts in cardiology, cardiovascular surgery, organ transplantation, infectious disease, and immunology. The three major considerations were: (1) experience with a clinical heart transplant program within the past five years, (2) adequate patient selection criteria, and (3) acceptable patient management plans and protocols. These points, discussed in detail in the *Federal Register*, are similar to the requirements for a cardiac transplantation program described by Copeland and Stinson.[5]

All participating clinical centers have agreed to furnish, or make available, a wide variety of data on heart transplants performed there, including information on their facilities and personnel resources, heart donor program, patient selection criteria, transplant and patient care protocols, patient follow-up care, patient survival, and patient charges.

Payment for Heart Transplants

As part of the study, the Health Care Financing Administration will pay for a total of 15 heart transplants. The recipients must, however, be Medicare beneficiaries at the time they receive the transplant. To qualify for Medicare benefits a patient must be over age 65 or have been declared disabled for at least two years. Thus, because of the current age restrictions, any patient eligible for such payment under the study guidelines must have been declared disabled.

Other factors that would preclude payment for a heart transplant under the study guidelines include: advancing age (eg, beyond the age [normally about 50] at which the individual begins to have a diminished capacity to withstand postoperative complications), severe pulmonary hypertension, irreversible and severe hepatic or renal dysfunction, active systemic infection, and any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation. A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen is an additional contraindication. These selection criteria have been described in considerable detail in the heart transplantation literature.[6-10]

At this time the study protocol calls for the 15 heart transplants to be distributed evenly among the six participating medical centers. Thus, each will be expected to do two heart transplants and the remaining three will probably be distributed on a first-come, first-served basis. Responsibility for deciding on patient eligibility for a heart transplant under the study will ultimately rest with the Health Care Financing Administration.*

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*Further information on the National Heart Transplantation Study may be obtained by writing to: Roger W. Evans, Ph.D., Research Scientist, Health and Population Study Center, Battelle Human Affairs Research Centers, 4000 N.E. 41st St., Seattle, WA 98105.

APPENDIX B

THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY
STUDY DESCRIPTION, STATEMENT OF OBJECTIVES,
AND PROJECT SIGNIFICANCE

Part I

THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY

STUDY DESCRIPTION, STATEMENT OF OBJECTIVES AND PROJECT SIGNIFICANCE

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Editor's Note: As an article prepared exclusively for the readers of Contemporary Dialysis, the Battelle Human Affairs Research Centers is presenting the first report on its important NKDKT Study to be published anywhere. It uses cost-effective criteria for analyzing various treatment forms for end-stage renal disease (ESRD), center and home hemodialysis, peritoneal dialysis and transplantation. Much has been written about the advantages and disadvantages of each of the therapies, but such a uniform and comprehensive study evaluating the impact of each form of treatment on quality of life, including the financial cost of that therapy, is necessary. The investigators acknowledge the limitations of the study (described in detail in Part II), which are that the centers were not selected by probability sampling procedures (although the patients within the centers were selected randomly), the study is cross-sectional rather than longitudinal, and cost data collection methods are imprecise. In addition, assessing the influences of staff manipulation of the treatment on its outcome is not included. However, the NKDKT Study is clearly important, unique and significant.

The National Kidney Dialysis and Kidney Transplantation (NKDKT) Study is a two-year cooperative study that is still being conducted (the results will be ready in January, 1983), involving almost 1,000 patients (325 home, 335 in-center, 140 peritoneal dialysis and 151 transplant [951]) at 11 dialysis and/or transplant centers across the United States. The major objective of the study is to collect and analyze data necessary to better understand the current status of chronic renal disease patients. In particular, the study focuses on five major areas: (1) quality of life, (2) rehabilitation, (3) disability, (4) quality of care, and (5) cost of treatment, including out-of-pocket medical expenditures. The absence of information on these areas, and the author's inability to ascertain the cost-effectiveness of alternative approaches to the treatment of kidney diseases are evidence of the need for this study. The following article describes the current state of the renal care field at the facilities, and the reasons for and contents of this study.

Recent studies have indicated that chronic renal disease patients experience high levels of disability, are inadequately rehabilitated and enjoy a relatively low quality of life.[1–3] There is some evidence to suggest that rehabilitation and quality of life are related to the type of therapy a patient is on.[4–6] For example, many studies show that home hemodialysis patients and kidney transplant patients generally experience a higher quality of life than patients on in-center hemodialysis. The nature of this relationship is suspect, however, since it is acknowledged that selection biases enter into the assignment of patients to therapy.[7–10] This can happen because patients placed on home hemodialysis as well as those who receive kidney transplants are often in better health than patients placed on in-center hemodialysis. Thus, before asserting a direct relationship between the type of therapy and the quality of a patient's life, it is important to take pretreatment patient differences into account.

Since there have been relatively few *systematic* large-scale studies which examine the effect that type of therapy has on patient quality of life, it has been difficult for the dialysis and transplant community, as well as the federal government, to decide which types of therapy should be given priority. Existing reports on the lower costs and greater advantages of home dialysis have undoubtedly influenced the position of the federal government which, in the absence of unequivocal results, has chosen to endorse transplantation and self-dialysis.[11] Public Law 95-292 (June 13, 1978) also makes this Federal position clear as does, to some extent, the Proposed ERSD Prospective Reimbursement Rate Regulations.

Although most persons would agree that home dialysis and transplantation have certain distinct advantages over in-center dialysis, it is evident that *all* types of therapy for chronic renal disease have evolved to meet the special needs of certain patients.[8] Reviews on the status of various types of therapy for chronic renal disease have recently appeared in the literature, confirming the fact that one type of therapy should not be promoted to the complete exclusion of the others.[5, 12-16]

In order that future health policies adequately reflect the needs of chronic renal disease patients, insure the highest standards of practice within the medical community, and promote the most effective use of public resources, the National Kidney Dialysis and Kidney Transplantation Study was undertaken. Rather than simply explore the direct relationship between type of therapy and patient quality of life, it was determined that a more exhaustive analysis was required in order to properly examine the direct and indirect relationships of various patient characteristics, including sociodemographic factors, health status, functional impairment, work disability, social environment, and type of therapy on the quality of a patient's life.

Quality of life is primarily defined in terms of the patient's level of life satisfaction, happiness, and general well-being, although it is acknowledged that disability and rehabilitation are frequently conceptualized as an integral part of the patient's quality of life matrix. Problems in measuring quality of life are well-documented in the literature.[17-23]

The scope of this study is not limited solely to the analysis of quality of life parameters, but it also involves a critical examination of the allocation of resources to and within the kidney disease program. The role that public pressure has played in influencing the allocation of scarce medical funds and resources to the ESRD program is acknowledged.

Questions, though, are increasingly being raised about the cost of the kidney disease program, its accountability and benefits directly derived by patients. The focus of our particular research efforts are on the cost-effectiveness of various approches (types of therapy) to the treatment of kidney diseases: home hemodialysis, facility or in-center hemodialysis, continuous ambulatory peritoneal dialysis (CAPD) or continuous cycling peritoneal dialysis (CCPD), and kidney transplantation.

To facilitate the process of making critical allocation decisions, information on both the efficacy of various treatments and their costs must be made available to decision makers in a systematic fashion that will allow them to make valid comparisons among alternative uses of those resources earmarked for the kidney disease program. To implement the conclusions from these comparisons, incentives must be offered to providers and patients alike to adopt cost-effective medical practices.[24-28] The cost-effectiveness analysis framework is particularly well-suited to the National Kidney Dialysis and Kidney Transplantation Study, wherein quality of life indicators must be incorporated with measures of the cost of treating kidney disease.[25, 27-31]

OBJECTIVES

The objectives of the NKDKT Study are as follows:

- To determine the impact of the type of therapy for renal disease on the quality of life of the patient;
- To incorporate quality of life measures with cost of care indicators to permit a cost-effectiveness analysis of various approaches to the treatment of kidney disease;
- To determine the impact of the type of therapy for renal disease on the quality of care for the patient;
- To describe and quantify the nature and extent of disability among dialysis and transplant patients;
- To assess the potential for improving the lives of dialysis and transplant patients by changes in types of therapy or through the provision of rehabilitation services;
- To examine the opportunity costs and out-of-pocket costs borne by ESRD patients and their families;
- To document nonremunerated costs borne by dialysis and transplant facilities; and
- To identify costs borne by third party payors.

SIGNIFICANCE

Despite the billion-dollar cost of the ESRD Program, little is known about the attributes and consequences of the program beyond the financial costs. This study addresses that gap by examining the effect of alternative types of therapy on the lives of the patients treated. The significance of the proposed research is evidenced by the following:

- The study is directed at a primary goal of the ESRD legislation: improving the rehabilitation and quality of life of ESRD patients;
- No systematic study has yet been made of the impact of therapy on the quality of life of ESRD patients;
- To encourage appropriate therapies for dialysis patients, professionals and public officials need to know about the tradeoffs among quality of life, quality of care, and treatment costs of alternative therapies;
- The study will contribute to the development of more effective ways to achieve rehabilitation of dialysis patients and to return them to normal productive lives for the remainder of their lives;
- Information will be obtained on the extent of unmet needs for therapy and rehabilitation of patients;
- The results of this study should afford an opportunity to improve patient well-being by appraising the benefits of various therapies in relation to their costs;
- This study represents one of the few attempts to document comprehensively the total cost of ESRD, including the out-of-pocket expenses borne by patients, as well as the nonremunerated costs borne by dialysis and transplant centers;
- Finally, this study seeks to assess the total cost of ESRD comparatively under four alternative types of therapy—in-center hemodialysis, home hemodialysis. CAPD, and transplantation.

SAMPLE DESIGN

The 11 dialysis and transplant centers selected to participate in this study constitute what is commonly referred to as a "purposive sample" and is distinctly different from a "probability sample." A purposive sample is a nonprobability sample and as such, one must be careful in making inferences from this sample of centers to the entire population of dialysis and transplant centers in the United States. We selected these 11 centers because they have characteristics which are critical to our analyses. For example, we selected centers to maximize variation among them for the following criteria:

- Geography (state/region);
- Type (limited care/full-care/both);
- Ownership (for-profit/nonprofit/state government);
- Size (number of dialysis stations);
- Academic affiliation (university based/nonuniversity based);
- Number of patients by type of therapy; and
- Service area (urban/rural).

Selecting Patients: All continuous ambulatory peritoneal dialysis (CAPD) or continuous cycling peritoneal dialysis (CCPD) patients are included in the sample. It has been necessary, however, to select a random sample of home hemodialysis patients, in-center hemodialysis patients and kidney transplant patients. Our goal, ultimately, is to interview 325 home hemodialysis patients, 325 in-center hemodialysis patients, 150 CAPD or CCPD patients and 150 kidney transplant patients.

DATA SOURCES

Data for this study are being obtained from multiple sources through several data collection instruments. The data sources include the patient, the patient's medical record, and the patient's primary nephrologist, social worker or renal nurse familiar with the patient's functional status. The data collection instruments are described below:

1. The *Chronic Renal Disease Patient Interview Schedule* is an interviewer-administrated data collection instrument that takes approximately 90 minutes to complete, and is the primary data collection instrument for the study. The interview occurs at the dialysis or transplant center or, in some cases, the patient's home.

2. The *Chronic Renal Disease Patient Health, Medical Care, and Treatment Expenses Diary* is a booklet each patient is asked to maintain for one month. The patients are asked to keep a record of illness behavior, utilization of health services, medical expenditures, and a daily record of how well they follow their diet, the extent to which they exercise and how well they feel. We acknowledged at the outset that responses to the patient diary are likely to be lower than desired, because the period of time for which they are being asked to keep the diary is lengthy and the types of data are complex. Nevertheless, there is a clear need to collect these data in a more systematic manner than previous attempts.

3. The *Chronic Renal Disease Patient Medical Records Data Abstraction Form* is intended to obtain pertinent medical data from the patient's chart (with the patient's written consent); a data collector for the study carries out this abstraction process. In addition, the patient's primary nephrologist, a social worker, or a renal nurse familiar with the patient's functional status records what comorbid (for example, diabetes) conditions a patient has and to what extent these impair the patient; an assessment is also made of the patient's ability to work.

4. The *Dialysis and Transplant Center Survey* obtains data on various dialysis and transplant center characteristics. This instrument is jointly completed by the medical director and administrator of each center, with appropriate input from the social work and nursing staff.

5. In addition to the above data sources, we also have access to the Medicare-billed charges data for each Medicare-eligible patient included in the study. These data are maintained through the Health Care Financing Administration's End-Stage Renal Disease Medical Information System. ☐

Editor's Note: Roger W. Evans, PhD, a medical sociologist, scientist and research principal investigator of the $500,000 NKDKT Study, is also principal investigator of the $553,000 National Heart Transplant Study still being conducted, and has presented and published a number of papers on ESRD-related topics. He is currently a special consultant of the Site Visit Team of the NIH National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; special consultant for the HCFA ESRD Program, and member of the National ESRD Rehabilitation Task Force. Louis P. Garrison, Jr., PhD *(bachelor's and doctoral degrees in economics), a research scientist at Battelle, has been involved in extensive medical studies.* Diane L. Manninen, PhD *(bachelor's degree in mathematics, MA and PhD in geography), is also a research scientist at Battelle, and has been involved in medical, labor and nuclear power socioeconomic studies.*

Questions and correspondence concerning the NKDKT Study should be directed to Roger W. Evans, PhD, Battelle Human Affairs Research Centers, Health and Population Study Center, 4000 N.E. 41st St., Seattle, WA 98105.

Watch for Part II of the National Kidney Dialysis and Kidney Transplantation Study in the August issue of **Contemporary Dialysis.**

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"Letters to HCFA"

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a reliable foundation on which to base reimbursement rates for FY 1983. Similarly, *HHS cannot support the assumption that* the limited cost data from less than five percent of facilities with home dialysis programs (including 10 of the 13 largest home programs) form a reliable foundation on which to base prospective rates.

2. *HHS cannot support the assumption that* the use of home dialysis is principally affected by the reimbursement system and paying physicians and facilities a "bounty" for home patients will significantly increase the use of home dialysis.
3. *HHS cannot support the assumption that* home dialysis is medically appropriate for 30–40 percent of the US dialysis population over the next five to seven years.
4. *HHS cannot support the assumption that* home dialysis is significantly less expensive than efficient in-center dialysis.
5. *HHS cannot support the assumption that* for purposes of setting a prospective rate for the first year of this new reimbursement system, use of the *median* of the cost data is appropriate.
6. *HHS cannot support the assumption that* the impact of the new system in paying 46 to 60 percent of the hospital-based facilities and 28 to 40 percent of independent facilities less than their costs, will not materially affect access to care and deprive Medicare beneficiaries of their entitlements.
7. *HHS cannot support the assumption that* economic efficiency, innovation and competition are promoted by the proposed composite, dual rate reimbursement system. . . .

The solution is two fold: first, set the rates at a realistic level which does not underreimburse all facilities and which provides an incentive for low-cost providers to expand and replace high-cost providers; and secondly, eliminate the exception process completely, or at least eliminate the "isolated essential facility" criterion. In fact, we would submit that elimination of the present exception rates would save a tremendous amount of Medicare dollars and would make the system more equitable and competitive. . . .

Home Dialysis: HHS places an enormous confidence in home dialysis as a more acceptable mode of therapy than in-center dialysis as well as the principal means for cost savings to Medicare. There is no evidence to support this confidence, and the data and experience that are available demonstrate that home dialysis is not a panacea for patients or the public.

The keystone of the policy shift announced in the NPRM is the strongly held belief by HHS that home dialysis is significantly less expensive than in-center dialysis, yet the HHS data clearly contradict this belief. As previously mentioned, the $97 median cost of home dialysis is suspect, because the sample included only five percent of all home dialysis programs and the sample was heavily weighted in favor of the largest and most efficient programs. Moreover, the cost evaluation did not include universally recognized auxiliary costs associated with home dialysis, namely: (1) the cost of hospitalization associated with higher morbidity among home patients; (2) certain capital and operating costs such as plumbing and electrical construction costs and additional utility expenses which are not included in the costs of the home dialysis sponsor; and (3) the opportunity cost of labor furnished by a family member who assists the patient on dialysis. Moreover, it's not clear from the NPRM whether the cost of the equipment is included in the $97 figure. It also is important to note that the 17 percent of the dialysis population currently using home dialysis is a very select group of patients. As the home patient population expands, sicker, older and poorer patients will be added to this population, and the median cost can be expected to increase substantially. A more comprehensive study conducted by the GAO which tracked the cost of home care for 308 patients concluded that the median cost of such care was $105.34 per treatment, again based on the present selective sample of healthier patients. . . .

Finally, we believe that the additional $20 per treatment proposed for self-care training to be grossly inadequate, and to the extent it underreimburses facilities for self-care training costs, the proposal disincents facilities from encouraging home dialysis. The one-on-one training ratio and the necessity of having a top quality instructor who can teach and motivate patients cost far more than $20 per treatment. . . .

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Part II
CONCLUSION
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THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY

STUDY DESCRIPTION, STATEMENT OF OBJECTIVES AND PROJECT SIGNIFICANCE

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The NKDKT Study is sponsored by the Office of Research and Demonstrations of the Health Care Financing Administration, Grant No. 95-P-97887/0-01.

The data to be collected for this study can conveniently be grouped into 13 categories. These categories and an exhaustive list of variables to be measured are provided in Table I.

Where feasible, we have used standard measures of those variables most critical to the study (e.g., quality of life, health status). These have been used for two reasons: (1) the reliability and validity of these measure are known; and (2) the availability of comparison groups on these measures (e.g., people with other chronic diseases, the general population). Furthermore, our use of measures with demonstrated reliability and validity has saved considerable irreplaceable time and resources (a complete listing of the standard measures incorporated in this study, an indication of previous surveys in which the measures have been used, and citations to the appropriate literature are all provided in Table II).

The issue of comparison groups is also important. This study is not experimental in the sense that patients are randomly assigned to experimental and control groups to see what effect the type of therapy has on patient quality of life, rehabilitation and disability. In other words, the study is not a clinical trial intended to identify the most efficacious treatment for chronic renal disease. Although we plan to prepare frequency distributions and scale scores for all patient groups, the desirability of comparing the responses of ESRD patients with those of the general population or with those of other chronically ill patients is obvious.

Thus, by using the standard measures which have had wide application elsewhere, we enhance our ability to make comparisons across these other groups. Unfortunately, most studies of chronic renal disease patients have failed to include comparison groups, such as nondialyzed renal patients, nonrenal chronic medical patients and nonpatients. Our use of standard measures represents an effort to clos this gap.[3]

DATA ANALYSIS

Although the analyses performed in this study are primarily directed toward testing two multivariate statistica models (one concerning the quality of life of ESRD patient and the other concerning the quality of care they receive) the model-testing exercise represents the final stage in multiple-stage approach to data analysis. Simple descriptiv statistics are used to answer the following types o questions:

- What is the quality of life of ESRD patients?
- How has or has not ESRD impacted on the family of th patient?
- What is the level of disability (as measured by functiona indices) of ESRD patients?
- What proportion of ESRD patients can be expected t return to work?
- What proportion of ESRD patients do return to work?
- What rehabilitation services are available to ESR patients?
- What percent of ESRD patients were working before th onset of their condition?
- How markedly is the health status of ESRD patients a fected following a kidney transplant?

In providing answers to the above questions, no attempt i made to explain how the means, proportions, or other mea sures of central tendency are affected by other variables in multivariate model. From a policy perspective the foregoin are more important questions to be answered. For exampl in attempting to justify the existence of a health program or policy, the policymaker is often called on to demonstrate the efficacy of the program. This is frequently achieved by citing statistics on the level of disability and rehabilitation of the people served under the program. However, when questions of efficacy are not answered straightforwardly (e.g., what type of therapy is best for ESRD?); there is ambiguity concerning the study results and attempts must be made to provide plausible explanations. From the perspective of the data analyst, this is when questions of a bivariate or multivariate nature must be addressed. The following questions fall in this category:

- What type of therapy maximizes the rehabilitation and quality of life of ESRD patients?
- How does the health status of the ESRD patient impact on family life?
- How does the patient's health status affect his/her ability to work?
- In what way does disability affect the ESRD patient's ability to work?
- Does a supportive social environment enhance the probability that an ESRD patient will return to work?
- How do various demographic variables affect the patient's quality of life and ability to return to work?
- Is functional impairment among ESRD patients differentially affected by various sociodemographic variables?

These questions represent attempts to answer or further address questions where the study results may be ambiguous and defy ready interpretation.

Still another level of analysis pursued involves the testing of multivariate models wherein the relationships among several variables are investigated. As already noted, two such models are postulated, one dealing with quality of life and one with quality of care. These causal models, as we might refer to them, force us to state testable multivariate hypotheses. Analytically they are more complex than simply examining bivariate relationships or the statement of simple descriptive statistics. Their complexity derives from the fact that multiple variables are analyzed simultaneously in an effort to understand better the direct, indirect and total effect that variables have on each other. For example, the quality of life model which we plan to test states that type of therapy both directly and indirectly affects the quality of a patient's life. Other variables in this model include: sociodemographic characteristics, health status, functional impairment and socioenvironmental characteristics (see Figure 1). This model suggests that quality of life is a function of several variables and that the relationships *among* these variables is worthy of consideration.

The quality of care model involves the analysis of slightly fewer variables and suggests that, for purposes of this study, there are four viable indicators of the quality of care a patient receives. These are mortality, hospital admissions, number of days hospitalized and physician visits or other contacts (e.g., telephone calls) the patient makes to the dialysis or transplant center.

TABLE I
INDEX OF DATA REQUIREMENTS

1. Quality of Life
   - life satisfaction
   - well-being
   - happiness
2. Type of Modality of Therapy
   - in-center hemodialysis (including self-care)
   - home hemodialysis
   - continuous ambulatory pertioneal dialysis (including continuous cycling peritoneal dialysis)
   - Transplantation
3. Disability
   - types and levels of patient disability
   - work limitations
   - frequency of disability days
   - limitations in activities of daily living
   - experience with disability benefit programs
4. Rehabilitation
   - use of rehabilitation services
   - experience with government benefit programs
   - experience with job training programs
5. Work
   - work history
   - employment status
   - kind of work (work characteristics)
6. Health Status
   - comorbidity
   - illness days
   - perceived health
   - satisfaction with health
   - anginaccess problems
7. Utilization of Health Services
   - number of hospital admissions
   - number of days hospitalized
   - contact with dialysis and transplant center staff (including telephone)
   - use of outpatient services
8. Income and Assets
   - income (source and amount)
   - assets
9. Expenditures
   - out-of-pocket health care expenditures
   - drug use and expenditures (prescription and nonprescription drugs)
   - payments to doctors, clinics, and hospitals
   - Medicare charges data
   - amount paid by third parties for treatments and drugs
   - payments for miscellaneous medically-related expenditures
10. Impact of Treatment
    - impact upon the family
    - impact upon social activities
11. Social Support
    - support from family and relatives
    - friendships and associations
12. Medical and Treatment
    - diagnosis
    - patient adherence to treatment regimens (including daily diet record)
    - type of dialyzer used
    - square meter hours of dialysis
    - kidney transplant experience
    - kidney disease treatment history
    - postdialysis syndrome
    - time of dialysis
    - level of daily exercise
13. Facility and Center-Based Data
    - Patient eligibility data (number of Medicare and non-Medicare patients)
    - facility operation data (number of shifts and operating days per week)
    - patient load data (breakdown of number of patients by type of therapy)
    - treatment load data (breakdown of number of treatments by type of therapy)
    - transplant data (number of patients transplanted, approximate survival rates)
    - rehabilitation program components (services provided, arrangements between the center and the community)
    - other considerations (hospital or freestanding unit, nonprofit or for-profit status, number of dialysis stations, dialyzer reuse, delivery system, staff turnover)

TABLE II

STANDARD MEASURES OF VARIABLES IN THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY

VARIABLE	PREVIOUS SURVEY AND/OR INDEX NAME	REFERENCES
Quality of Life (Life Satisfaction)		
• Standard of Living	The Quality of American Life Study	18
• Life as a Whole		19, 20
• Savings and Investments		22
• Family Life		
• Friendships		
• Marriage		
Quality of Life (Well-Being)		
• General Sense of Well-Being		32
• General Well-Being	General Well-Being Schedule,	33
	Health Interview Survey	34
• Positive and Negative Affect		35
• Index of Well-Being	The Quality of American Life Survey	22
Quality of Life (Happiness)	National Commission on Mental Illness	36
• Level of Happiness	and Health Survey; The Quality of	35
	American Life Survey	22
Quality of Life (Life in General)		
• General Life Satisfaction		37
• General Life Satisfaction	The Quality of American Life Survey	22
Functional Impairment		
• Specific Impairments	Rand Corp., Health Insurance Survey	38, 39
• Specific Impairments	1978 SSA Disability Survey	40-42, 43, 44
• General Composite Index	Karnofsky Index	45,46, 2
Work Limitations		
• Kind and Amount	Health Interview Survey; National Medical Care	47
	Expenditures Survey; National Medical Care	48
	Utilization and Expenditures Survey	
Manifest Symptons of Physical and Emotional Limitations	1978 SSA Survey of Disability and Work	40, 41, 43, 44, 49, 50, 31
Health Status	Sickness Impact Profile	52 - 54, 55 - 57
• Sleep and Rest		
• Emotional Behavior		
• Body Care and Movement		
• Home Maintenance		
• Mobility		
• Social Interaction		
• Ambulation		
• Alertness Behavior		
• Communication		
• Work		
• Recreation and Pasttimes		
• Eating		
Hospitalization		
• Number of Hospital Admissions	Health Interview Survey	47
• Number of Days Hospitalized		
Family and Social Support	Rand Corp. Health Insurance Study	58
Independence/Dependence	The Gift of Life Survey	59
Employment Status	The Renal Dialysis Study	60, 61
Occupation		62
• Type of Work		
• Employer		
• Business and Industry		
Income		
• Level	1978 SSA Survey of Disability and Work	43, 44, 50, 51
Utilization of Disability Benefits Program	1978 SSA Survey of Disability and Work	43, 44, 50, 51
Utilization of Rehabilitation Services	1978 SSA Survey of Disability and Work	43, 44, 50, 51
Job Training Program	1978 SSA Survey of Disability and Work	43, 44, 50, 51

In addition to the usual quality of care outcomes cited here, we also are considering other variables as proxy measures of quality of care. For example, postdialysis syndrome is a problem for many dialysis patients. Some patients have suggested that central dialysis delivery systems magnify postdialysis symptoms and, in return, result in a lower quality of life. Like quality of life, the quality of medical care cannot be easily defined or described, as it is predicated on value systems, standards and perspectives which vary from person to person, group to group and place to place.

These perspectives, however, must be addressed in providing the care which is desired and needed. The quality of life and the quality of medical care, as described by Cluff, however, both have a common objective, and that is its optimal or maximal personal function.[17] Consequently, the preceding variables, despite obvious limitations, serve as our "indicators" of the quality of care a patient receives. Within our model the quality of care a patient receives is seen as a function of three classes of variables: personal characteristics (e.g., age, sex, race), structural features of the dialysis or transplant center (e.g., treatment load, number of procedures performed, size of staff, etc.), and the type of therapy a patient receives. Our goal, nevertheless, is to determine how quality of care is affected by these variables.*

LIMITATIONS OF THE STUDY

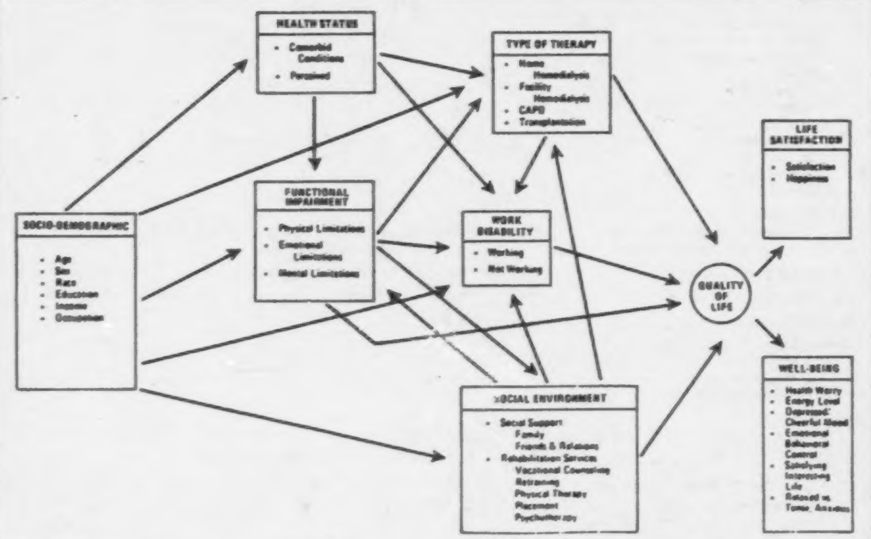
This study, like any other, has certain limitations. Acknowledging these limitations is important to the interpretation of the study results which also serves to point out the direction of future research.

The first limitation is that the 11 dialysis and transplant centers participating in this study were not selected on the basis of probability sampling procedures. Thus, it is inappropriate to infer that the results of the study apply to all centers and patients in the United States. Therefore, in a statistical sense, the problem is one of inference. If we had a probability sample of patients across the United States, we would be able to generalize our results from the sample to the entire population. Unfortunately, this is not the case. Nevertheless, it is noteworthy that the major objective of this study is *not* to make comparisons across dialysis and transplant centers. For example, we are not concerned with how well patients at center A and center B are doing, comparatively speaking. Instead, we are only concerned with being able to estimate quantities regarding the whole sampling frame.

Our second major problem stems from the fact that the study is cross-sectional rather than longitudinal. A *cross-sectional* study design involves the collection of data at one point in time, whereas a *longitudinal* design involves the collection of data at several points in time. Most studies are cross-sectional because longitudinal studies are very expensive to conduct. Yet, a cross-sectional design makes it very difficult to ascertain what existed or what occurred before the point at which the data were collected.[7, 8, 10]

The problems engendered by a cross-sectional design, however, are at least partially resolvable. Patients on various types of therapy, for example, can be matched on numerous salient criteria (e.g., age, sex, race, socioeconomic status, presence of comorbidity, etc.) and then compared to exam-

FIGURE 1
A THEORETICAL SOCIOMEDICAL MODEL OF THE QUALITY OF LIFE OF DIALYSIS PATIENTS


HEALTH STATUS
Comorbid Conditions
Perceived
TYPE OF THERAPY
Home Hemodialysis
Facility Hemodialysis
CAPD
Transplantation
LIFE SATISFACTION
Satisfaction
Happiness
FUNCTIONAL IMPAIRMENT
Physical Limitations
Emotional Limitations
Mental Limitations
SOCIO-DEMOGRAPHIC
Age
Sex
Race
Education
Income
Occupation
WORK DISABILITY
Working
Not Working
QUALITY OF LIFE
WELL-BEING
Health Worry
Energy Level
Depressed: Cheerful Mood
Emotional Behavioral Control
Satisfying Interesting Life
Relaxed vs. Tense, Anxious
SOCIAL ENVIRONMENT
Social Support
Family
Friends & Relatives
Rehabilitation Services
Vocational Counseling
Retraining
Physical Therapy
Placement
Psychotherapy

ine the effect varying types of therapy have on the outcomes of interest. This approach, in many regards, approximates the major methodological objectives of case control studies in epidemiology that are frequently cited in cancer-related research.[64, 65]

A third limitation of the study is related to the relative absence of facility-based data which reflect staff attitude to the general problem of patient rehabilitation. Although it could be argued that the staff of a dialysis or transplant center can have a major influence on patient outcomes, this study does not document these influences in any great detail. The study does, however, inquire about the provision of rehabilitation services and who had responsibility for arranging them.

Perhaps the last significant limitation of the study is with regard to the source of our cost (i.e., charge) data. Many people have criticized the data maintained through the End-Stage Renal Disease Medical Information System.[31] Although these data are clearly inadequate for some purposes, they are the best data available to us to perform the required cost analyses. Every attempt is being made to insure and enhance the quality of the data, but to collect new data for this study would be infeasible and beyond the current availability of resources. ☐

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*All models are abstractions, and the models presented here contain a relatively large number of variables. By definition the models are incomplete, but no model is completely able to explain all of the variance in the event or phenomenon under study. Consequently, it is relatively easy to suggest other variables that are relevant to our proposed models. Part of the model testing exercise repostulates the models to the extent that the appropriate data are available.

Author's Note: A project the size of the National Kidney Dialysis and Kidney Transplantation Study involves the contributions of many and is acknowledged by the authors. Drs. Marilyn Bergner, Christopher R. Blagg, John C. Crowley, Robert A. Gutman, Alan R. Hull, Edmund G. Lowrie and Thomas L. Marchioro all serve on the Advisory Committee for the project. The project secretary is Mildred Gregory. Data collectors for each participating center are: The Kidney Center (Boston), Tina Zuckman; Dallas Kidney Disease Center, Evelyn Warren, Carolyn Hamm, Dee Ann Taylor; Northwest Kidney Center, Elena Andresen, Gina Gross, Marilyn Hoe and Cynthia Livak; Nalle Clinic Kidney Center, Tricia Ward; Eastern Maine Hospital, Julie LaCombe; Presbyterian Medical Center, Robert Zelanes; West Contra Costa Dialysis Center, Fern Stone; Bishop-Clarkson Memorial Hospital, Debra Sanders; Indiana University Medical Center, Lucy Hardison; Dialysis Clinics, Inc., Suzanne Jiran; Downstate Medical Center, Ellen Pincus and Roberta Temes. A major contribution in time and effort is also being made by the medical, nursing, social work and administrative staff at each center. We sincerely appreciate the efforts of all involved, and finally, we are especially grateful to the patients who have given of their time to participate in the study.

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Continued from page 13

bowel obstruction as a cause of previously unexplained chronic, recurrent abdominal pain, nausea and vomiting not related to infection.

Although the peritoneal air contrast study has proven to be relatively free of complications, it is recommended that in the presence of poor dialysate drainage or active intraabdominal problems, cannulography precede nitrous oxide insufflation. Upon completion of the procedure or in the event of severe abdominal pain, contrast media and nitrous oxide should be removed. ☐

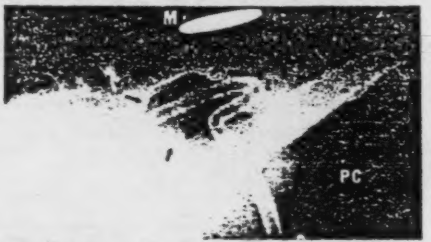

Figure 3A: Subcutaneous collection of air (arrows); (M = marker on umbilicus; PC = peritoneal cavity).

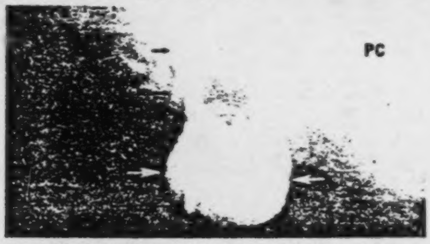

Figure 3B: Contrast media (dark arrows) has drained from the peritoneal cavity (PC), along the catheter, and into a large cavity (white arrows): (cross-table roentgenogram taken with patient in hands and knees position).

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APPENDIX C

SELECTION CRITERIA FOR HEART DONORS

Variables Relevant to the Selection of Heart Donors

1) DONOR AGE

2) CAUSE OF DEATH
   - trauma
   - CVA
   - brain tumor
   - drug overdose
   - cardiopulmonary arrest
   - other

3) TYPE OF DEATH
   - brain death
   - cardiac death

4) LOCATION OF DEATH
   - hospital
   - other

5) ASSOCIATED DISEASE
   - hypertension
   - diabetic
   - malignancy
   - sepsis
   - arteriosclerosis
   - other cardiac disease
   - other (specify)______________________________

6) DONOR SEX

7) INTRACARDIAC INJECTIONS DURING RESUSCITATION

8) CONTRAINDICATIONS
   - history of transient, severe hypotension after injury
   - known ECG abnormalities
   - murmurs on physical exam

9) RESTRICTED CONSENT FOR ORGAN DONATION
   - Kidneys
   - Corneas
   - Skin
   - Heart
   - Liver
   - Lungs
   - Pancreas
   - Body

Variables Relevant to the Selection of Heart Donors (continued)

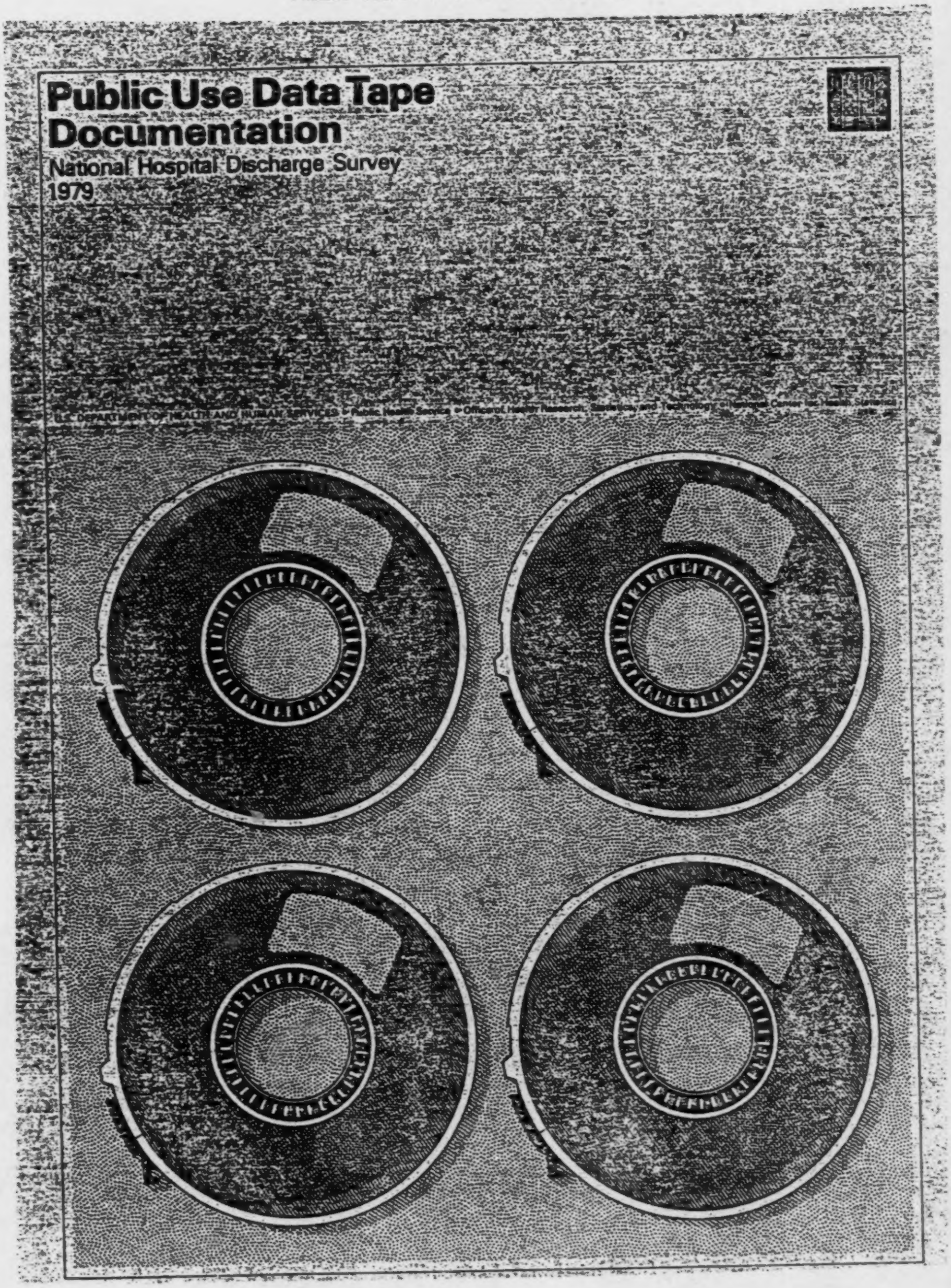
10) INFECTIONS
    - Pulmonary
    - Genitourinary
    - Subcutaneous
    - Abdominal
    - CNS
    - Systemic

11) DRUGS ADMINISTERED IN LAST 24 HOURS
    - isuprel
    - aramine
    - intropin
    - mannitol
    - epinephrine

12) CHEST X-RAY RESULTS
    - widened mediastinum
    - pneumothorax
    - rib fractures
    - pneumonia

APPENDIX D

NATIONAL CENTER FOR HEALTH STATISTICS
NATIONAL HOSPITAL DISCHARGE SURVEY
PUBLIC USE DATA TAPE DOCUMENTATION



Public Use Data Tape Documentation

National Hospital Discharge Survey
1979

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • Public Health Service • Office of Health Research, Statistics, and Technology • National Center for Health Statistics

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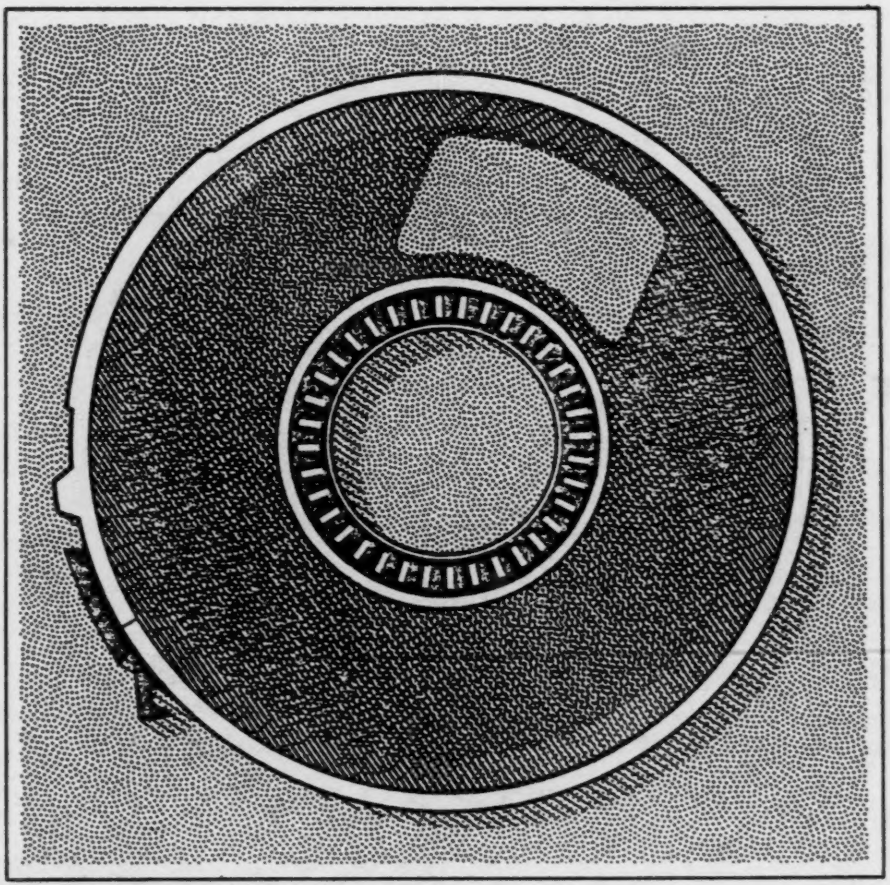
Public Use Data Tape Documentation

National Hospital Discharge Survey
1979



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Office of Health Research, Statistics, and Technology
National Center for Health Statistics

Hyattsville, Maryland
August 1981

Errata:

1. In section III. Tape Record Format, the variable Principal Expected Source of Payment is missing. It should be included as item number 26 in tape location 131 (1 position) with the following legend:

   1: Self-pay
   2: Workmen's Compensation
   3. Medicare
   4. Medicaid
   5. Other government payments
   6. Blue Cross
   7. Other private or commercial insurance
   8. No charge
   9. Other
   0. Not stated

2. Item number 22, Number of Beds (NMFI), does not exist on the tape.

3. Item number 24, Hospital Ownership (NMFI), does not exist on the tape.

1979 NATIONAL HOSPITAL DISCHARGE SURVEY (NHDS)
MICRO-DATA TAPE DOCUMENTATION

ABSTRACT

This material provides documentation for users of the Micro-Data Tapes of the NHDS conducted by the National Center for Health Statistics (NCHS). Section I, "Description of the National Hospital Discharge Survey," includes information on the history of the NHDS, the scope of the survey, the sample, data collection procedures, medical coding procedures, population estimates, measurement errors and sampling errors. Section II provides technical details of the tape (number of tracks, record length, etc.). Section III provides a detailed description of the contents of each data record, by location. Appendix A defines certain terms used in this document, Appendix B provides population estimates to allow the user to calculate rates, and Appendix C lists Class 4 surgical procedures not coded by NHDS.

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I. DESCRIPTION OF THE NATIONAL HOSPITAL DISCHARGE SURVEY

INTRODUCTION.--This document and its attachments allow one to use the 1979 micro-data tape which contains the data collected by the National Hospital Discharge Survey conducted by the National Center for Health Statistics. The National Hospital Discharge Survey provides a continuous sample of hospital discharge records, collecting medical and demographic information for calculating statistics on hospital utilization. The survey consists of data abstracted from the face sheets of the medical records for sampled inpatients discharged from a national sample of non-federal short-stay hospitals. For a description of the survey design and data collection procedures, see below. For a more detailed description of the survey design, data collection procedures, and the estimation process, see Reference 1.

HISTORY.--To provide more complete and precise information on the utilization of the Nation's hospitals and on the nature and treatment of illness among the hospitalized population, the NCHS in 1962 began exploring possibilities for surveying morbidity in hospitals. A national advisory group was established. The NCHS conducted planning discussions with other elements of the Public Health Service. Hospitalization material from the Survey Research Center of the University of Michigan, the American Hospital Association, and the Professional Activities Study was examined and evaluated. In 1963, a study by the School of Public Health of the University of Pittsburgh under contract to the NCHS demonstrated the feasibility of an NHDS type of program. An additional pilot study using enumerators from the Bureau of the Census was conducted in late 1964 and confirmed the University of Pittsburgh's findings.

Finally, with advice and support from the American Hospital Association, the American Medical Association, individual experts, other professional groups, and elements of the Public Health Service, NCHS initiated the National Hospital Discharge Survey in 1964.

SCOPE OF THE SURVEY.--The National Hospital Discharge Survey encompasses patients discharged from noninstitutional hospitals, exclusive of Federal hospitals, located in the 50 States and the District of Columbia. For purposes of the NHDS, a facility is considered a short-stay hospital only if it meets the following criteria:

1. At least six beds are maintained for use by inpatients.
2. It is licensed as a hospital in States with licensure laws.
3. Inpatient medical care is provided under the supervision of a licensed doctor of medicine or osteopathy.
4. Nursing service is provided 24 hours a day under supervision of a registered nurse.
5. Separate medical records are maintained for each patient admitted.
6. The average length of stay for all patients is less than 30 days.

SAMPLING FRAME AND SIZE OF SAMPLE.--The National Master Facility Inventory of Hospitals and Institutions (NMFI) constitutes the sampling frame (universe) for hospitals in the NHDS. NCHS has published a detailed description of the NMFI, its contents, plans for maintaining it, and procedures for assessing the completeness of its coverage (see Reference 2). The universe for the survey consisted originally of 6,965 short-stay hospitals, excluding military and VA hospitals, contained in the NMFI in 1963.

The sample of hospitals for 1970-1979 are shown in Table 1. In each year, some hospitals refuse to participate and some are deemed out of scope, either because the hospital had gone out of business or because it failed to meet the NHDS definition of a short-stay hospital. The number of hospitals which refuse to participate or are out of scope are also given in Table 1, along with the number of participating hospitals. The sample increased in several of the years to accommodate new hospitals.

Table 1

Year	Number of Hospitals			
	Sampled	Refused	Out of Scope	Surveyed
1970	465	46	24	395
1971	465	60	26	379
1972	497	45	28	424
1973	497	42	31	424
1974	497	38	33	426
1975	511	44	35	432
1976	511	53	39	419
1977	535	68	44	423
1978	535	74	48	413
1979	544	65	48	431

SAMPLE DESIGN.--All hospitals with 1,000 beds or more in the universe of short-stay hospitals were selected with certainty in the sample. All hospitals with fewer than 1,000 beds were stratified, the primary stratum being the 24 size-by-region classes shown in Table 2. Within each of these 24 primary strata, the allocation of the hospitals was made through a controlled selection technique so that hospitals in the sample would be properly distributed with regard to type of ownership and geographic division. Sample hospitals were drawn with probabilities ranging from certainty for the largest hospitals to 1 in 40 for the smallest hospitals.

The within-hospital sampling ratio for selecting sample discharges varied inversely with the probability of selection of the hospital. The smallest sampling fraction of discharged patients was taken in the largest hospitals, and the largest fraction was taken in the smallest hospitals. This was done to compensate for the fact that hopsitals were selected with probabilities proportionate to their size class and to assure that the overall probability of selecting a discharge would be approximately the same in each size class.

Table 2. Distribution of short-stay hospitals in the universe (Master Facility Inventory) and in the National Hospital Discharge Survey sample and the number of hospitals that participated in the survey, by geographic region and bed size of hospital: United States, 1979

Bed Size of Hospital	All Regions	North-east	North Central	South	West
All Sizes		Number of Hospitals			
Universe....................	8,017	1,784	2,148	3,196	1,489
Total sample................	544	132	153	176	83
Number participating........	431	110	116	143	62
6-49 Beds					
Universe....................	3,521	223	899	1,670	729
Total sample................	70	8	18	30	14
Number participating........	44	6	13	19	6
50-99 Beds					
Universe....................	1,897	301	486	737	373
Total sample................	80	14	20	32	14
Number participating........	61	11	14	25	11
100-199 Beds					
Universe....................	1,411	298	412	479	222
Total sample................	122	26	34	43	19
Number participating........	99	22	27	34	16
200-299 Beds					
Universe....................	624	195	166	165	98
Total sample................	98	31	27	24	16
Number participating........	76	26	20	18	12
300-499 Beds					
Universe....................	411	113	134	111	53
Total sample................	98	25	32	29	12
Number participating........	86	22	26	29	9
500-999 Beds					
Universe....................	135	45	48	29	13
Total sample................	58	19	19	13	7
Number participating........	48	15	13	13	7
1,000 Beds or More					
Universe....................	18	9	3	5	1
Total sample................	18	9	3	5	1
Number participating........	17	8	3	5	1

In nearly all hospitals, the daily listing sheet of discharges was the frame from which the subsamples of discharges were selected within the sample hospitals. The sample discharges were selected by a random technique, usually on the basis of the terminal digit(s) of the patient's medical record number--a number assigned when the patient was admitted to the hospital. If the hospital's daily discharge listing did not show the medical record number, the sample was selected by starting with a randomly selected discharge and taking every kth discharge thereafter.

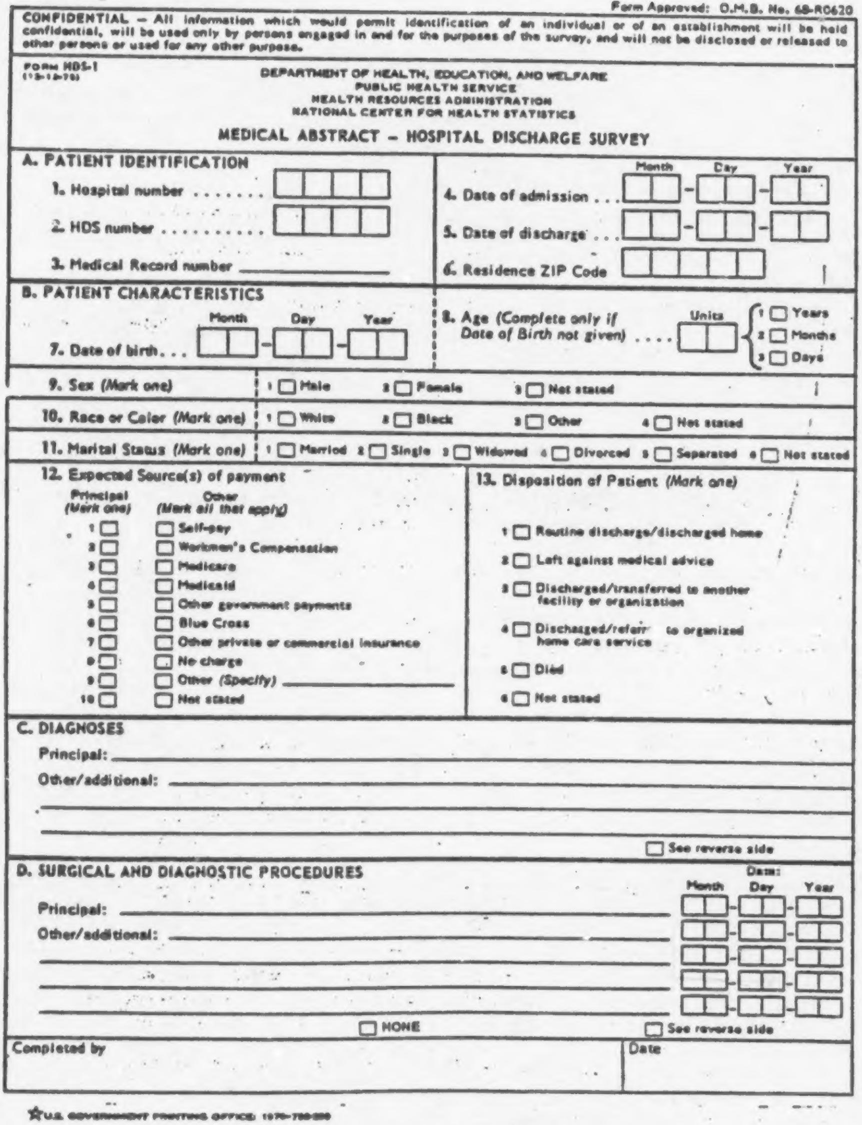
DATA COLLECTION.--Depending on the study procedure agreed on with the hospital administrator, either hospital staff or representatives of the NCHS performed the sample selection and the transcription of information from the hospital records to abstract forms. The abstract form used for 1979 is shown in Figure 1. In about two-thirds of the hospitals that participate in the NHDS, the medical records department of the hospital performed this work. In the remaining hospitals, personnel of the U.S. Bureau of the Census acting for NCHS performed the work.

Survey hospitals used an abstract form to transcribe data from the hospital records. The abstract form provides for recording demographic data, admission and discharge dates, discharge status, and information on discharge diagnoses and surgical operations or procedures. All discharge diagnoses were listed on the abstract form in the order of principal diagnosis, or first-listed diagnosis if the principal diagnosis was not identified, followed by the order in which all other diagnoses were entered on the face sheet of the medical record. All operations were listed in the order in which they were recorded on the face sheet.

Shipments of completed abstract forms for each sample hospital were transmitted, along with sample selection control sheets, to a Census Regional Office. Every shipment of abstracts was reviewed and each abstract form was checked for completeness. Abstracts were then sent to NCHS for processing.

MEDICAL CODING AND EDIT.--The medical information recorded on the sample patient abstracts was coded centrally by NCHS staff. A maximum of seven diagnostic codes was assigned for each sample abstract; in addition, if the medical information included surgery, a maximum of four codes for surgical operations and procedures was assigned. Following the conversion of the data on the medical abstract to computer tape, a final medical edit was accomplished by computer inspection runs and a review of rejected abstracts. If sex or age of patient was incompatible with the recorded medical information, priority was given to the medical information in the editing decision.

The basic system for coding the diagnoses on NHDS sample patient abstracts is the ICD-9-CM (see Reference 3). The ICD-9-CM section for Surgical Operations, Diagnostic and Other Therapeutic Procedures is the coding system used for surgical procedures and operations.



Form Approved: O.M.B. No. 68-R0620

CONFIDENTIAL – All information which would permit identification of an individual or of an establishment will be held confidential, will be used only by persons engaged in and for the purposes of the survey, and will not be disclosed or released to other persons or used for any other purpose.

FORM HDS-1
([illegible])

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH RESOURCES ADMINISTRATION
NATIONAL CENTER FOR HEALTH STATISTICS

MEDICAL ABSTRACT – HOSPITAL DISCHARGE SURVEY

A. PATIENT IDENTIFICATION

1. Hospital number .... ☐☐☐☐
2. HDS number .... ☐☐☐☐
3. Medical Record number ________

4. Date of admission ... Month ☐☐ - Day ☐☐ - Year ☐☐
5. Date of discharge ... Month ☐☐ - Day ☐☐ - Year ☐☐
6. Residence ZIP Code ☐☐☐☐☐

B. PATIENT CHARACTERISTICS

7. Date of birth ... Month ☐☐ - Day ☐☐ - Year ☐☐

8. Age *(Complete only if Date of Birth not given)* .... Units ☐☐ 1 ☐ Years 2 ☐ Months 3 ☐ Days

9. Sex *(Mark one)* 1 ☐ Male 2 ☐ Female 3 ☐ Not stated

10. Race or Color *(Mark one)* 1 ☐ White 2 ☐ Black 3 ☐ Other 4 ☐ Not stated

11. Marital Status *(Mark one)* 1 ☐ Married 2 ☐ Single 3 ☐ Widowed 4 ☐ Divorced 5 ☐ Separated 6 ☐ Not stated

12. Expected Source(s) of payment

Principal *(Mark one)*	Other *(Mark all that apply)*
1 ☐	☐ Self-pay
2 ☐	☐ Workmen's Compensation
3 ☐	☐ Medicare
4 ☐	☐ Medicaid
5 ☐	☐ Other government payments
6 ☐	☐ Blue Cross
7 ☐	☐ Other private or commercial insurance
8 ☐	☐ No charge
9 ☐	☐ Other *(Specify)* ________
10 ☐	☐ Not stated

13. Disposition of Patient *(Mark one)*

1 ☐ Routine discharge/discharged home
2 ☐ Left against medical advice
3 ☐ Discharged/transferred to another facility or organization
4 ☐ Dischaged/referr to organized home care service
5 ☐ Died
6 ☐ Not stated

C. DIAGNOSES

Principal: ________
Other/additional: ________
____
____

☐ See reverse side

D. SURGICAL AND DIAGNOSTIC PROCEDURES

	Date: Month	Day	Year
Principal: ________	☐☐	☐☐	☐☐
Other/additional: ________	☐☐	☐☐	☐☐
________	☐☐	☐☐	☐☐
________	☐☐	☐☐	☐☐
________	☐☐	☐☐	☐☐

☐ NONE ☐ See reverse side

Completed by
Date

☆U.S. GOVERNMENT PRINTING OFFICE: 1979-[illegible]

Figure I. Medical Abstract for the National Hospital Discharge Survey

The Uniform Hospital Discharge Data Set (UHDDS) classifies ICD-9-CM procedures into 4 classes. Classes 1-3 consist of "significant procedures" - that is, procedures which carry an operative or anesthetic risk or require highly trained personnel, special facilities, or special equipment. Class 4 procedures are not considered significant; therefore, reporting them is considered optional. The NHDS collects data on only three class 4 procedures: circumcision (code 64.0); episiotomy (code 73.6); and removal of intrauterine contraceptive device (97.1). Other class 4 procedures are not coded by NHDS and are listed in Appendix C.

POPULATION ESTIMATES.--Appendix B contains population estimates provided by the U.S. Bureau of the Census. The estimates cover the U.S. civilian noninstitutionalized population on July 1 of the data year. These population estimates are consistent with those published in Current Population Reports, Series P-25; however, these tables are not official population estimates of the Bureau of the Census.

MEASUREMENT ERRORS.--As in any survey, results are subject to nonsampling or measurement errors, which include errors due to hospital nonresponse, missing abstracts, information incompletely or inaccurately recorded on abstract forms, and processing errors. Less than 1 percent of the discharge records failed to include age or sex of patient. However, race was not stated for about 13 percent of all discharges. If the hospital record did not state age or sex of patient, it was imputed by assigning the patient an age or sex consistent with the age or sex of other patients with the same diagnostic codes. When the record did not include race, it was identified as "not stated." If the dates of admission or discharge were not given, and if they could not be obtained from the monthly sample listing sheet transmitted by the sample hospital, a length of stay was imputed by assigning the patient a stay characteristic of the stays of other patients of the same age. In addition, nonresponse (about 8 percent) for principal expected source of payment was imputed to reflect similarities in sex and age.

SAMPLING ERRORS.--Procedures for calculating sampling errors are described in detail in Reference 1. Estimates of standard errors for a particular year calculated from NHDS data are available in the appendix of NHDS publications for that year. These publications are available from the address given immediately below.

HOW TO USE THE DATA TAPE.--The NHDS records are weighted to allow inflation to national or regional estimates. The weight applied to each record is found in tape location 111-115. To produce an estimate of the number of discharges, the weights for the desired records must be summed. To produce an estimate for number of days of care, the weight must be multiplied by the length of stay (tape location 101-104) and these products are summed. Length of stay data can be obtained by using recodes already on the tape (see items 17 and 21 in the tape layout), or by dividing days of care by number of discharges as calculated above.

QUESTIONS.--Questions concerning data in the tapes should be directed to the Hospital Care Statistics Branch, Division of Health Care Statistics, National Center for Health Statistics, Center Building, Room 2-43, 3700 East-West Highway, Hyattsville, Maryland 20782.

REFERENCES

[1] National Center for Health Statistics: Development of the design of the NCHS Hospital Discharge Survey, by W. R. Simmons. Vital and Health Statistics. PHS Pub. No. 1000, Series 2-No. 39. Public Health Service. Washington. U.S. Government Printing Office, Sept. 1970.

[2] National Center for Health Statistics: Development and maintenance of a national inventory of hospitals and institutions. Vital and Health Statistics. PHS Pub. No. 1000, Series 1-No. 3. Public Health Service. Washington. U.S. Government Printing Office, Feb. 1965.

[3] National Center for Health Statistics: International Classification of Diseases, Ninth Revision, Clinical Modification. DHHS Pub. No. (PHS) 80-1260. Public Health Service. Washington. U.S. Government Printing Office, Sept. 1980.

II. TECHNICAL DESCRIPTION OF TAPE

Data Set Name--NHDS.YR1979
Number of Reels--------------------------------------1
Number of Recording Tracks---------------------------9
Density (bpi)--1600
Language---EBCDIC
Parity---Odd
Record Length--200
Block Size---8000
Number of Records------------------------------------215,243

III. TAPE RECORD FORMAT

This section consists of a detailed breakdown of each tape record, providing a brief description of each item of data included in the records. The data are arranged sequentially according to their physical location on the tape record. Unless otherwise stated in the Item Description, the data are derived from the abstract form. The NMFI and the hospital interview are alternate sources of data, while the computer generates other items.

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979 OUTLINE OF ITEMS AND CODES ARRANGED BY LOCATION IN THE FINAL MEDICAL TAPE RECORD

Item Number	Tape Location	Number of Positions	Item Description and Codes
1	1	1	Sample Frame 1: Admission List 2: Discharge List
	2-8	7	Blank
2	9-10	2	Control Month This code is either the month of admission or discharge depending upon the sample frame used in a hospital as coded in Location 1. 01: January through 12: December
	11-12	2	Blank
3	13-14	2	Century of Birth (18 or 19)
	15-24	10	Blank
4	25-30	6	Date of Birth This item is used to calculate age at date of admission, if it passes the edit. (This item appears in the output record as it was in the input record except in the case of month imputed as 06 and/or day imputed as 15).

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes	
4.1	25-26	2	Month of Birth	
4.2	27-28	2	Day of Birth	
4.3	29-30	2	Year of Birth	
			00-79: 1900-1979	
			80-99: 1880-1899	
5	31-33	3	Age	
			Units (Location 33)	Number (Location 31-32)
			1: Years	01-99
			2: Months	01-11
			3: Days	00-28
6	34	1	Sex	
			1: Male	
			2: Female	
	35	1	Blank	
7	36	1	Marital Status	
			1: Married	
			2: Single	
			3: Widowed	
			4: Divorced	
			5: Separated	
			6: Not Stated	
			7: Unknown	

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes
8	37-41	5	Date of Admission (Imputed according to age if invalid or blank.)
8.1	37-38	2	Month of Admission 01: January through 12: December
8.2	39-40	2	Day of Admission 01-31
8.3	41	1	Year of Admission 8: 1978 9: 1979
9	42-46	5	Date of Discharge (Imputed according to age if invalid or blank.)
9.1	42-43	2	Month of Discharge 01: January through 12: December
9.2	44-45	2	Day of Discharge 01-31
9.3	46	1	Year of Discharge 9: 1979 0: 1980
10	47	1	Discharge Status 1: Routine discharge/discharged home 2: Left against medical advice 3: Discharged/transferred to another facility or organization 4: Discharged/referred to organized home care service 5: Dead 6: Not Stated 9: Not Stated

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes
	48	1	Blank
11	49	1	Age Recode 1: Less than 15 2: 15-44 3: 45-64 4: 65 and over
12	50	1	Number of Diagnostic Codes Recorded 1-Minimum 7-Maximum
13	51	1	Number of Surgery Codes Recorded 0-Minimum 4-Maximum
14	52-56	5	Date of Surgery #3
14.1	52-53	2	Month of Surgery 01-12
14.2	54-55	2	Day of Surgery 01-31
14.3	56	1	Year of Surgery 8: 1978 9: 1979 0: 1980
15	57-61	5	Date of Surgery #4 Same format as above (52-56)
	62-77	16	Blank

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes
16	78-81	4	Length of Stay in Days This item was generated in the computer on the basis of date of admission and date of discharge. In case of blank or invalid date of admission and/or date of discharge, this item was imputed according to age. Codes range from 0000 to 0730.
17	82-83	2	Length of Stay Recode #1 (Computer Generated) 00: 00 Days 01: 01 Days .... 31: 31 Days and over
18	84-85	2	Age Recode (Computer Generated) 00: Newborn 01: Under 1 Year 02: 01-04 Years 03: 05-14 Years 04: 15-24 Years 05: 25-34 Years 06: 35-44 Years 07: 45-54 Years 08: 55-64 Years 09: 65-74 Years 10: 75 Years and over
19	86	1	Race Recode (Computer Generated) 1: White 2: All Other 3: Not Stated

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes
20	87	1	Marital Status Recode (Computer Generated) 1: Married 2: Not Married 3: Not Stated
21	88	1	Length of Stay Recode #2 (Computer Generated) 1: 00-07 Days 2: 08-14 Days 3: 15-21 Days 4: 22-28 Days 5: 29 Days and Over
	89	1	Blank
22	90	1	Number of Beds Recode (NMFI) 1: 6-49 Beds 2: 50-99 Beds 3: 100-199 Beds 4: 200-299 Beds 5: 300-499 Beds 6: 500-999 Beds 7: 1,000 Beds or More
23	91	1	Geographic Region (NMFI) 1: Northeast 2: North Central 3: South 4: West

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes
24	92	1	Hospital Ownership (NMFI) 1: Proprietary 2: Church 3: Government 4: Nonprofit, Excluding Church
25	93	1	Geographic Division Northeast Region 1: New England 2: Middle Atlantic North Central Region 3: East North Central 4: West North Central South Region 5: South Atlantic 6: East South Central 7: West South Central West Region 8: Mountain 9: Pacific
	94-98	5	Blank
26	99	1	Number of Beds Recode (Interview) 1: 6-49 Beds 2: 50-99 Beds 3: 100-199 Beds 4: 200-299 Beds 5: 300-499 Beds 6: 500-999 Beds 7: 1,000 Beds or More

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes
27	100	1	Hospital Ownership (Interview) 1: Proprietary 2: Church 3: Government 4: Nonprofit, Excluding Church
28	101-104	4	Length of Stay in Days Data in 78-81 has been transferred to this data field with 0000 days recoded to 0001.
	105-110	6	Blank
29	111-115	5	Weight Final adjusted weight (whole number--used in table preparation)
	116-130	15	Blank
30	131-136	6	Expected Source(s) of Payment
30.1	131	1	Principal No. 1
30.2	132	1	Principal No. 2
30.3	133	1	Other No. 1
30.4	134	1	Other No. 2
30.5	135	1	Other No. 3
30.6	136	1	Other No. 4

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes
			Code Source of Payment
			1: Self-Pay
			2: Workman's Compensation
			3: Medicare
			4: Medicaid
			5: Other Government Payment
			6: Blue Cross
			7: Other Private or Commercial Insurance
			8: No Charge
			9: Other
			0: Not Stated
31	137-141	5	Date of Surgery #1
31.1	137-138	2	Month of Surgery 01-12
31.2	139-140	2	Day of Surgery 01-31
31.3	141	1	Year of Surgery 8: 1978 9: 1979 0: 1980
32	142-146	5	Date of Surgery #2 Same format as above (137-141)
	147-148	2	Blank

NATIONAL HOSPITAL DISCHARGE SURVEY - 1979

Item Number	Tape Location	Number of Positions	Item Description and Codes
33	149-183	35	Diagnostic Codes* (5-Digit Codes)
33.1	149-153	5	Diagnosis No. 1**
33.2	154-158	5	Diagnosis No. 2**
33.3	159-163	5	Diagnosis No. 3**
33.4	164-168	5	Diagnosis No. 4**
33.5	169-173	5	Diagnosis No. 5**
33.6	174-178	5	Diagnosis No. 6**
33.7	179-183	5	Diagnosis No. 7**
34	184-199	16	Surgical Codes* (4-Digit Codes)
34.1	184-187	4	Surgery No. 1
34.2	188-191	4	Surgery No. 2
34.3	192-195	4	Surgery No. 3
34.4	196-199	4	Surgery No. 4
	200		Blank

*Codes are in compliance with the new International Classification of Diseases-9th Revision-Clinical Modification (ICD-9-CM). All codes are left justified. The symbol, "-", a dash, is used to fill all fourth and fifth spaces where three- or four-digit diagnostic codes are used and to fill all fourth spaces where three-digit surgical codes are used.

**Codes can be preceded by the following symbols:

In Text		On Tape File
E	appears as	)
V	appears as	=

APPENDIX A

DEFINITIONS OF CERTAIN TERMS USED IN THIS DOCUMENT

Hospitals.--Short-stay special and general hospitals having six beds or more for inpatient use and an average length of stay of less than 30 days. Federal hospitals and hospital units of institutions are not included.

Bed size of hospital.--Measured by the number of beds, cribs, and pediatric bassinets regularly maintained (set up and staffed for use) for patients; bassinets for newborn infants are not included.

Type of ownership of hospital.--The type of organization that controls and operates the hospital. Hospitals are grouped as follows:

> Voluntary nonprofit.--Hospitals operated by a church or another nonprofit organization.
>
> Government.--Hospitals operated by State or local governments.
>
> Proprietary.--Hospitals operated by individuals, partnerships, or corporations for profit.

Patient.--A person who is formally admitted to the inpatient service of a short-stay hospital for observation, care, diagnosis, or treatment.

Discharge.--The formal release of a patient by a hospital, that is, the termination of a period of hospitalization by death or by disposition to place of residence, nursing home, or another hospital.

Discharge diagnosis.--One or more diseases or injuries (or special conditions and examinations without sickness or tests with negative findings) that the attending physician assigns to the medical record of patients. (See "Medical Coding and Edit," page 5.)

Operation.--One or more surgical operations, procedures, or special treatments that are assigned by the physician to the medical record of patients discharged from the inpatient service of short-stay hospitals. (See "Medical Coding and Edit," page 5.)

Age.--Patient's age refers to age at birthday prior to admission to the hospital inpatient service.

Race.--Patients are classified into the three groups listed in the Tape Record Format under Race (item #19).

Geographic region and division.--Hospitals are classified by location into one of the four geographic regions and nine geographic divisions of the United States (items #23 and #25 in the Tape Record Format), which correspond to those used by the U.S. Bureau of the Census.

Appendix B

Civilian noninstitutionalized population by sex, age, and geographic region: United States, July 1, 1979

(Population estimates consistent with Series P-25, Current Population Reports, U.S. Bureau of the Census)

Age and Region	Both Sexes	Male	Female
	Population in thousands		
All Ages	215,884	104,180	111,704
Northeast	48,232	23,138	25,094
North Central	57,515	28,021	29,493
South	69,941	33,486	36,456
West	40,193	19,533	20,660
0-14 Years	50,092	25,563	24,530
Under 1 year	3,279	1,679	1,600
1-4 years	12,362	6,319	6,043
5-14 years	34,451	17,564	16,887
Northeast	10,416	5,324	5,092
North Central	13,433	6,862	6,570
South	16,766	8,540	8,226
West	9,477	4,836	4,641
15-44 Years	98,941	48,197	50,744
15-24 years	40,162	19,760	20,402
25-34 years	34,099	16,570	17,528
35-44 years	24,680	11,866	12,813
Northeast	21,679	10,577	11,102
North Central	26,588	13,128	13,460
South	31,808	15,303	16,506
West	18,865	9,189	9,676
45-64 Years	43,481	20,786	22,695
45-54 years	22,747	10,995	11,752
55-64 years	20,734	9,792	10,943
Northeast	10,543	4,986	5,557
North Central	11,331	5,468	5,863
South	13,665	6,462	7,203
West	7,942	3,870	4,072
65 Years and Over	23,369	9,634	13,735
65-74 Years	14,950	6,505	8,445
75 years and over	8,419	3,129	5,290
Northeast	5,594	2,251	3,343
North Central	6,163	2,563	3,600
South	7,702	3,181	4,521
West	3,909	1,638	2,271

Appendix C

UHDDS Class 4 Procedures Not Coded by NHDS

01.18-01.19
03.39
04.19
05.19
06.19
07.19
08.19
08.91-08.93
09.19
09.41-09.49
10.29
11.29
12.29
14.19
15.09
16.21
16.29
18.01
18.11
18.19
20.39
21.21
21.29
22.19
24.19
25.09
25.91
26.19
27.29
27.91
28.19
29.19
31.48-31.49
33.28-33.29
34.28-34.29
37.29
38.29
40.19
41.30-41.39
42.29
44.19
45.19
45.28-45.29
48.23
48.29
49.21
49.29
49.41
50.19
51.19

52.19
54.29
55.29
56.39
57.39
58.29
59.29
60.18
61.19
62.19
63.09
64.00
64.19
64.91
64.94
65.19
66.19
67.19
68.19
69.92
70.21
70.29
71.19
73.60
73.91-73.92
75.35
76.19
78.80-78.89
81.98
83.29
85.19
86.19
86.92
87.09-87.12
87.16-87.17
87.22-87.29
87.36-87.37
87.39
87.43-87.49
87.69
87.79
87.85-87.89
87.92
87.95-87.99
88.09
88.16-88.31
88.33
88.35
88.37
88.39

89.01-89.13
89.15-89.16
89.26-89.31
89.33-89.39
89.45-89.53
89.55-89.59
89.66
89.70
90.01-91.99
93.01-93.25
93.27-93.28
93.31-93.39
93.42-93.44
93.61-93.91
93.94
93.96
93.99-94.23
94.25
94.29-95.03
95.05-95.11
95.14-95.15
95.31-95.49
96.09-96.19
96.26-96.28
96.34-97.04
97.14-97.89
9~~7~~.02-99.24 9
99.26-99.59
99.71-99.79
99.82-99.99

APPENDIX E

NATIONAL HEART TRANSPLANTATION STUDY
POTENTIAL ORGAN DONOR SURVEY
GALLUP POLL

POTENTIAL ORGAN DONOR SURVEY
GALLUP POLL

1. Some people choose to donate their kidneys, hearts, livers, and other organs upon their death to others who need organ transplant operations. Before now have you ever heard about organ transplantation?

	(CIRCLE ONE)
YES	01
NO	02

2. The Uniform Anatomical Gifts Act permits an individual to sign a card donating his or her organs in case of death. Have you ever heard about or received information concerning organ donation?

	(CIRCLE ONE)
YES	01
No	02 (SKIP TO Q. 5)

3. Before today, from what sources have you learned about organ donations? (DO NOT READ, CIRCLE ALL THAT APPLY)

	(CIRCLE ALL THAT APPLY)
DOCTORS OR NURSES	01
TELEVISION	02
NEWSPAPERS AND MAGAZINES	03
RADIO	04
FRIENDS	05
LECTURES	06
BROCHURES AND PAMPHLETS	07
OTHER (INCLUDES DON'T KNOW)	08

4. Do you currently carry an organ donor card?

(CIRCLE ONE)

YES .... 01 (SKIP TO Q.6)

NO 02

5. Would you, if asked, be prepared to sign and carry an organ donor card?

(CIRCLE ONE)

YES 01

NO 02

6. If you had to make the decision, would you donate the organs of a relative who had just died?

(CIRCLE ONE)

YES 01

NO 02

7. If you were to die suddenly, do you think that your family would give permission for the removal of any of your organs for transplantation?

(CIRCLE ONE)

YES 01

NO 02

8. Next, I would like to find out which, if any, of the following organs you would be willing to donate. Would you be willing to donate...

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO
a.	KIDNEYS	01	02
b.	CORNEAS	01	02
c.	HEART	01	02
d.	LIVER	01	02
e.	LUNGS	01	02
f.	PANCREAS	01	02
g.	SKIN	01	02
h.	WHOLE BODY	01	02

9. Do you feel that if someone signs an organ donor card his or her decision should have to be formally approved by his next-of-kin when he dies ?

(CIRCLE ONE)

YES 01

NO 02

10. If the next-of-kin disapproves do you feel that their disapproval should override the potential donor's wishes as expressed on any organ donor card?

(CIRCLE ONE)

YES 01

NO 02

11. Do you feel that the next-of-kin should be allowed to donate the organs of relatives who have recently died but have not signed an organ donor card?

(CIRCLE ONE)

YES 01

NO 02

12. Do you feel that doctors should have the power to remove organs from people who have recently died but have not signed an organ donor card without consulting their next-of-kin?

(CIRCLE ONE)

YES 01

NO 02

13. Brain death is considered to occur when brain activity stops, although it is possible to continue heartbeat and respiration by artificial means. State laws may use brain death as the legal definition of death and will allow the removal of organs for transplantation, such as the heart, from persons pronounced dead on this basis. Do you feel that brain death should be used as the legal definition of death?

(CIRCLE ONE)

YES 01

NO 02

14. Do you feel that it is all right to remove organs for transplantation upon declaration of brain death?

(CIRCLE ONE)

YES 01

NO 02

APPENDIX F

NATIONAL HEART TRANSPLANTATION STUDY
ORGAN PROCUREMENT PROGRAM DATA COLLECTION FORM

PROGRAM/HOSPITAL: ______________________

NATIONAL HEART TRANSPLANTATION STUDY

ORGAN PROCUREMENT PROGRAM DATA COLLECTION FORM

☐☐☐ (1-3)

	DATE OF DEATH (Record Month, Day and Year)			AGE (Record in Years)	SEX (0-1)	PRIMARY CAUSE OF DEATH (Check One)						TYPE OF DEATH (Check One)		HEART FUNCTION ON ARRIVAL AT HOSPITAL (Check One)			ASSOCIATED DISEASE (Check All That Apply)										INFECTIONS (Check All That Apply)						DRUGS ADMINISTERED IN PAST 24 HOURS (Check All That Apply)						CHEST X-RAY RESULTS (Check All That Apply)				OTHER CONTRAINDICATIONS (Check All That Apply)						ORGANS CONSENTED FOR DONATION (Check All That Apply)								OTHER (Check All That Apply)					COMMENTS
	MONTH (4-5)	DAY (6-7)	YEAR (8-9)	DONOR AGE AT DEATH (10-11)	DONOR SEX (12)	TRAUMA (13)	CVA (14)	CARDIOPULMONARY ARREST (15)	DRUG OVERDOSE (16)	BRAIN TUMOR (17)	OTHER (18)	BRAIN DEATH (19)	CARDIAC DEATH (20)	ARREST (21)	PHARMACOLOGICAL SUPPORT (22)	NORMAL (23)	CONGENITAL CARDIAC DISEASE (24)	VALVULAR CARDIAC DISEASE (25)	ATHEROSCLEROTIC CARDIAC DISEASE (26)	PERIPHERAL ARTERIOSCLEROSIS (27)	DIABETES (28)	HYPERTENSION (29)	SEPSIS (30)	MALIGNANCY (31)	CHRONIC LUNG DISEASE (32)	OTHER (33)	SYSTEMIC (34)	PULMONARY (35)	CNS (36)	ABDOMINAL (37)	GENITO-URINARY (38)	SUBCUTANEOUS (39)	ISUPREL (40)	ARAMINE (41)	INTROPIN (42)	EPINEPHRINE (43)	OTHER INOTROPIC AGENTS (44)	MANNITOL (45)	WIDENED MEDIASTINUM (46)	PNEUMOTHORAX (47)	RIB FRACTURES (48)	PNEUMONIA (49)	SUSTAINED CARDIAC ARREST (50)	INTRACARDIAC INJECTIONS USED DURING RESUSCITATION (51)	HISTORY OF TRANSIENT SEVERE HYPOTENSION AFTER INJURY (52)	SEVERE INTRATHORACIC TRAUMA (53)	MURMURS ON PHYSICAL EXAM (54)	ECG ABNORMALITIES (55)	KIDNEYS (56)	CORNEAS (57)	HEART (58)	LIVER (59)	LUNGS (60)	PANCREAS (61)	SKIN (62)	BONE (63)	DONOR WAS CARRYING A DONOR CARD (64)	PERMISSION OF NEXT OF KIN WAS OBTAINED (65)	PERMISSION OF CORONER WAS OBTAINED (66)	LIFE-SUPPORT CONTINUED AFTER DECLARATION OF BRAIN DEATH (67)	HEART WAS OFFERED TO A HEART TRANSPLANT CENTER (68)	PLEASE PROVIDE ANY CLARIFYING COMMENTS ON EACH DONOR REFERRAL (69-80)
1																																																														
2																																																														
3																																																														
4																																																														
5																																																														
6																																																														
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11																																																														
12																																																														
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14																																																														
15																																																														

(1) IF A GIVEN TEST WAS NOT PERFORMED, FOR EXAMPLE, A CHEST X-RAY WAS NOT DONE, PLACE AN "NP" IN EACH COLUMN WHERE THE TEST RESULTS WERE TO BE RECORDED.

(2) PLACE A "DK" IN EACH COLUMN IF THE INFORMATION REQUESTED IS NOT KNOWN.

OMB ______________

APPENDIX G

NATIONAL HEART TRANSPLANTATION STUDY
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APPENDIX H

UNIFORM ANATOMICAL GIFT ACT

UNIFORM ANATOMICAL GIFT ACT

AN ACT authorizing the gift of all or part of a human body after death for specified purposes.

SECTION 1. [*Definitions.*]

(a) "Bank or storage facility" means a facility licensed, accredited, or approved under the laws of any state for storage of human bodies or parts thereof.

(b) "Decedent" means a deceased individual and includes a stillborn infant or fetus.

(c) "Donor" means an individual who makes a gift of all or part of his body.

(d) "Hospital" means a hospital licensed, accredited, or approved under the laws of any state; includes a hospital operated by the United States government, a state, or a subdivision thereof, although not required to be licensed under state laws.

(e) "Part" means organs, tissues, eyes, bones, arteries, blood, other fluids and any other portions of a human body.

(f) "Person" means an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(g) "Physician" or "surgeon" means a physician or surgeon licensed or authorized to practice under the laws of any state.

(h) "State" includes any state, district, commonwealth, territory, insular possession, and any other area subject to the legislative authority of the United States of America.

COMMENT

Subsection (f) is taken verbatim from the Uniform Statutory Construction Act, section 26 (4). In any state that has adopted the Uniform Act or its equivalent, this subsection will be unnecessary.

Subsection (h) is taken from section 26 (9) of the Uniform Statutory Construction Act.

SECTION 2. [*Persons Who May Execute an Anatomical Gift.*]

(a) Any individual of sound mind and 18 years of age or more may give all or any part of his body for any purpose specified in section 3, the gift to take effect upon death.

(b) Any of the following persons, in order of priority stated, when persons in prior classes are not available at the time of death, and in the absence of actual notice of contrary indications by the decedent or actual notice of opposition by a member of the same or a prior class, may give all or any part of the decedent's body for any purpose specified in section 3:

(1) the spouse,

(2) an adult son or daughter,

(3) either parent,

(4) an adult brother or sister,

(5) a guardian of the person of the decedent at the time of his death,

(6) any other person authorized or under obligation to dispose of the body.

(c) If the donee has actual notice of contrary indications by the decedent or that a gift by a member of a class is opposed by a member of the same or a prior class, the donee shall not accept the gift. The persons authorized by subsection (b) may make the gift after or immediately before death.

(d) A gift of all or part of a body authorizes any examination necessary to assure medical acceptability of the gift for the purposes intended.

(e) The rights of the donee created by the gift are paramount to the rights of others except as provided by Section 7 (d).

COMMENT

Existing state statutes differ in their respective standards establishing the donor's competence to execute an anatomical gift.

"Competence to execute a will" is used as the standard in 10 states. "Legal age" and sound mind is required in 5 states. "Twenty-one years and sound mind" is the stated standard in the statutes of 10 states. In 4 states a person who is 18 years of age or older may make the gift, and in 6 states "any person" may do so. One state requires 21 years accompanied by a certificate of a physician that the donor is "of sound mind and not under the influence of narcotic drugs."

To minimize confusion there is merit in having a uniform provision throughout the country. Also it is desirable to enlarge the class of possible donors as much as possible. Subsection (a) of Section 2, providing that any person of sound mind and 18 years or more of age may execute a gift, will afford both nationwide uniformity and a desirable enlargement of the class of donors. Persons 18 years of age or more are of sufficient maturity to make the required decisions and the Uniform Act takes advantage of this fact.

Subsection (b) spells out the right of survivors to make the gift. Taking into account the very limited time available following death for the successful removal of such critical tissues as the kidney, the liver, and the heart, it seems desirable to eliminate all possible question by specifically stating the rights of and the priorities among the survivors.

Also, Section 2 (b) provides for the effect of indicated objections by the decedent, and differences of view among the survivors. Finally it authorizes the survivors to execute the necessary documents even prior to death. In view of the fact that persons under 18 years of age are excluded from subsection (a), it is especially desirable to cover with care the status of survivors, so younger decedents may be included.

Subsection (d) is added at the suggestion of members of the medical profession who regard a post mortem examination, to the extent necessary to ascertain freedom from disease that might cause injury to the new host for transplanted parts, as essential to good medical practice.

Subsection (e) recognizes and gives legal effect to the right of the individual to dispose of his own body without subsequent veto by others.

SECTION 3. [*Persons Who May Become Donees; Purposes for Which Anatomical Gifts May be Made.*] The following persons may become donees of gifts of bodies or parts thereof for the purposes stated:

(1) any hospital, surgeon, or physician, for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation; or

(2) any accredited medical or dental school, college or university for education, research, advancement of medical or dental science, or therapy; or

(3) any bank or storage facility, for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation; or

(4) any specified individual for therapy or transplantation needed by him.

COMMENT

Existing state statutes reveal great diversity of provisions concerning possible donees and the purposes for which anatomical gifts may be made.

As to donees, the lists include licensed hospitals, storage banks, teaching institutions, universities, colleges, medical schools, state public health and anatomy boards, and institutions approved by the state department of health. Some of the statutes are detailed and comprehensive. Others are limited, brief, and general. A few do not seek in any way to name or limit the donees. The Uniform Act attempts to achieve a maximum of clarity and precision by carefully naming the permissible donees.

The statutes in a few states specify that no donor shall ask compensation and no donee shall receive it. Several statutes provide that storage banks shall be non-profit organizations. On the other hand, most of the states have chosen not to deal with this question. The Uniform Act follows the latter course in this regard.

As to purposes, again there is great diversity among the statutes. The list of purposes includes teaching, research, advancement of medical science, therapy, transplantation, rehabilitation, and scientific uses. Again some of the statutes are detailed, and others are brief and general. A few statutes contain no limitation whatsoever—merely naming the donees, thus assuring that gifts will not be made to undesirable persons or organizations, and then they are inclusive in naming the purposes in broad terms, thus assuring flexibility. The Uniform Act follows this course.

SECTION 4. [*Manner of Executing Anatomical Gifts.*]

(a) A gift of all or part of the body under Section 2 (a) may be made by will. The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated, or if it is declared invalid for testamentary purposes, the gift, to the extent that it has been acted upon in good faith, is nevertheless valid and effective.

(b) A gift of all or part of the body under Section 2 (a) may also be made by document other than a will. The gift becomes effective upon the death of the donor. The document, which may be a card designed to be carried on the person, must be signed by the donor [in the presence of 2 witnesses who must sign the document in his presence]. If the donor cannot sign, the document may be signed for him at his direction and in his presence in the presence of 2 witnesses who must sign the document in his presence. Delivery of the document of gift during the donor's lifetime is not necessary to make the gift valid.

(c) The gift may be made to a specified donee or without specifying a donee. If the latter, the gift may be accepted by the attending physician as donee upon or following death. If the gift is made to a specified donee who is not available at the time and place of death, the attending physician upon or following death, in the absence of any expressed indication that the donor desired otherwise, may accept the gift as donee. The physician who becomes a donee under this subsection shall not participate in the procedures for removing or transplanting a part.

(d) Notwithstanding Section 7 (b), the donor may designate in his will, card, or other document of gift the surgeon or physician to carry out the appropriate procedures. In the absence of a designation or if the designee is not available, the donee or other person authorized to accept the gift may employ or authorize any surgeon or physician for the purpose.

(e) Any gift by a person designated in Section 2 (b) shall be made by a document signed by him or made by his telegraphic, recorded telephonic, or other recorded message.

COMMENT

Most existing state statutes authorizing anatomical gifts provide for doing so either by will or by other document in writing. The number of witnesses varies from state to state, but the majority require two witnesses. The Uniform Act requires two witnesses to validate a gift during the donor's lifetime, but witnesses are relatively unnecessary in the case of a gift by next of kin since they are available in person. Hence, none are required in such cases. To facilitate availability of evidence of the gift, a card may be carried on the person, a practice commonly and successfully followed in connection with gifts of eyes. This is an important provision, for we are a peripatetic people and the advantages of a card carried on the person stating the donor's intention to donate is apparent.

Also important are the provisions of subsection (c) that permit the attending physician upon or following death to be the donee when no donee is named or when the named donee is not available. The donee physician cannot participate personally in removing or transplanting a part, but he can, of course, make a further gift to another person for any authorized purpose.

Attention should also be called to subsection (e) authorizing the next of kin to make gifts by "telegraphic, recorded telephonic, or other recorded message." Frequently the next of kin are far away, and this provision, not found in any existing statute, has the advantage of expediting the procedures where time for effective action is short.

As the Uniform Act becomes widely accepted it will prove helpful if the forms by which gifts are made are similar in each of the participating states. Such forms should be as simple and understandable as possible. The following forms are suggested for the purpose:

Anatomical Gift by a Living Donor

I am of sound mind and 18 years or more of age.

I hereby make this anatomical gift to take effect upon my death. The marks in the appropriate squares and words filled into the blanks below indicate my desires.

I give: ☐ my body; ☐ any needed organs or parts; ☐ the following organs or parts ______________________________;

To the following person (or institution): ☐ the physician in attendance at my death; ☐ the hospital in which I die; ☐ the following named physician, hospital, storage bank or other medical institution ______________ ______________; ☐ the following individual for treatment ______________ ______________________________;

for the following purposes: ☐ any purpose authorized by law; ☐ transplantation; ☐ therapy; ☐ research; ☐ medical education.

Dated ______________ City and State ______________

Signed by the Donor in the presence of the following who sign as witnesses:

____
Signature of Donor

____
Witness

____
Address of Donor

____
Witness

Anatomical Gift by Next of Kin or Other Authorized Person

I hereby make this anatomical gift of or from the body of ______________ ______________ who died on ______________ at the ______________ ______________ in ______________. The marks in the appropriate squares and the words filled into the blanks below indicate my relationship to the deceased and my desires respecting the gift.

I am the surviving: ☐ spouse; ☐ adult son or daughter; ☐ parent; ☐ adult brother or sister; ☐ guardian; ☐ ______________, authorized to dispose of the body;

I give ☐ the body of deceased; ☐ any needed organs or parts; ☐ the following organs or parts ______________________________;

To the following person (or institution) ______________________
(insert the name of a physician, hospital, research or educational institution, storage bank, or individual),

for the following purposes: ☐ any purpose authorized by law; ☐ transplantation; ☐ therapy; ☐ research; ☐ medical education.

Dated ______________ City and State ______________________

____
Signature of Survivor

____
Address of Survivor

SECTION 5. [*Delivery of Document of Gift.*] If the gift is made by the donor to a specified donee, the will, card, or other document, or an executed copy thereof, may be delivered to the donee to expedite the appropriate procedures immediately after death. Delivery is not necessary to the validity of the gift. The will, card, or other document, or an executed copy thereof, may be deposited in any hospital, bank or storage facility or registry office that accepts it for safekeeping or for facilitation of procedures after death. On request of any interested party upon or after the donor's death, the person in possession shall produce the document for examination.

COMMENT

Some of the statutes make rather formal mandatory provisions for filing of documents of gift. Thus in two states the gift must be "filed for record in the office of the judge of probate." In another the document must be filed either before death or within 60 hours after death with the State Department of Health. In another the instrument must be filed for record "in the office of the clerk of the district court of the parish wherein the person making the gift resides." In still another the instrument must be filed in the probate court. In two states it is provided that the instrument shall be delivered by the donor to the donee. On the other hand, in the great majority of the states, no provision is made for filing, recording, or delivery to the donee. The gift is by implication effective without such formality. Section 5 of the Uniform Act follows the majority permissive practice, but includes permissive filing provisions to expedite post-mortem procedures.

SECTION 6. [*Amendment or Revocation of the Gift.*]

(a) If the will, card, or other document or executed copy thereof, has been delivered to a specified donee, the donor may amend or revoke the gift by:

(1) the execution and delivery to the donee of a signed statement, or

(2) an oral statement made in the presence of 2 persons and communicated to the donee, or

(3) a statement during a terminal illness or injury addressed to an attending physician and communicated to the donee, or

(4) a signed card or document found on his person or in his effects.

(b) Any document of gift which has not been delivered to the donee may be revoked by the donor in the manner set out in subsection (a), or by destruction, cancellation, or mutilation of the document and all executed copies thereof.

(c) Any gift made by a will may also be amended or revoked in the manner provided for amendment or revocation of wills, or as provided in subsection (a).

Comment

In about one half of the states no provision is made for revocation. However, in the interest of carrying out the ultimate desires of the donor, there is good reason for facilitating revocation. Accordingly, about half of the states make affirmative provisions concerning the matter. Usually it is provided that revocation may be accomplished by executing a "like instrument" filed in the manner provided for the instrument of gift and delivered to the donee. In a few states revocation is accomplished by demanding return of the document of gift. There is merit in making revocation both simple and easy to accomplish. Prospective donors are more likely to look with favor on making anatomical gifts if they realize that revocation is readily possible. The Uniform Act makes careful and complete provision for revocation under various contingencies. However, if a donor has deposited an executed copy of an undelivered document of gift as authorized by Section 5, and if the donor desires to revoke the gift, he must see to it that the executed copy which has been deposited is destroyed.

Section 7. [*Rights and Duties at Death.*]

(a) The donee may accept or reject the gift. If the donee accepts a gift of the entire body, he may, subject to the terms of the gift, authorize embalming and the use of the body in funeral services. If the gift is of a part of the body, the donee, upon the death of the donor and prior to embalming, shall cause the part to be removed without unnecessary mutilation. After removal of the part, custody of the remainder of the body vests in the surviving spouse, next of kin, or other persons under obligation to dispose of the body.

(b) The time of death shall be determined by a physician who tends the donor at his death, or, if none, the physician who certifies the death. The physician shall not participate in the procedures for removing or transplanting a part.

(c) A person who acts in good faith in accord with the terms of this Act or with the anatomical gift laws of another state [or a foreign country] is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act.

(d) The provisions of this Act are subject to the laws of this state prescribing powers and duties with respect to autopsies.

COMMENT

Section 7 contains several important provisions. The donee may of course, reject the gift if he deems it best to do so. If he accepts the gift, all possible provision is made for taking account of the interests of the survivors in dignified memorial ceremonies. Also if the donee accepts the gift, absolute ownership vests in him. He may, if he so desires, transfer his ownership to another person, whether the gift be of the whole body or merely a part. He may "cause the part to be removed" either by himself or by another person. The only restrictions are that the part must be removed without mutilation and the remainder of the body vests in the next of kin.

Subsection (b) leaves the determination of the time of death to the attending or certifying physician. No attempt is made to define the uncertain point in time when life terminates. This point is not subject to clear cut definition and medical authorities are currently working toward a consensus on the matter. Modern methods of cardiac pacing, artificial respiration, artificial blood circulation and cardiac stimulation can continue certain bodily systems and metabolism far beyond spontaneous limits. The real question is when have irreversible changes taken place that preclude return to normal brain activity and self sustaining bodily functions. No reasonable statutory definition is possible. The answer depends upon many variables, differing from case to case. Reliance must be placed upon the judgment of the physician in attendance. The Uniform Act so provides.

However, because time is short following death for a transplant to be successful, the transplant team needs to remove the critical organ as soon as possible. Hence there is a possible conflict of interest between the attending physician and the transplant team, and accordingly subsection (b) excludes the attending physician from any part in the transplant procedures. Such a provision isolates the conflict of interest and is eminently desirable. However, the language of the provision does not prevent the donor's attending physician from communicating with the transplant team or other relevant donees. This communication is essential to permit the transfer of important knowledge concerning the donor, for example, the nature of the disease processes affecting the donor or the results of studies carried out for tissue matching and other immunological data.

Subsection (d) is necessary to preclude the frustration of the important medical examiners' duties in cases of death by suspected crime or violence. However, since such cases often can provide transplants of value to living persons, it may prove desirable in many if not most states to reexamine and amend, the medical examiner statutes to authorize and direct medical examiners to expedite their autopsy procedures in cases in which the public interest will not suffer.

The entire section 7 merits genuinely liberal interpretation to effectuate the purpose and intent of the Uniform Act, that is, to encourage and facilitate the important and ever increasing need for human tissue and organs for medical research, education and therapy, including transplantation.

SECTION 8. [*Uniformity of Interpretation.*] This Act shall be so construed as to effectuate its general purpose to make uniform the law of those states which enact it.

SECTION 9. [*Short Title.*] This Act may be cited as the Uniform Anatomical Gift Act.

SECTION 10. [*Repeal.*] The following acts and parts of acts are repealed:

(1)
(2)
(3)

SECTION 11. [*Time of Taking Effect.*] This Act shall take effect . . . .

NOTE:

By action of the commissioners at their Annual Conference in August, 1980 the following amendments were made:

1. Brackets [ ] were added to Section 4 (b) in lines 12 and 13 as indicated.

2. Existing lines 13 thru 16 of Comments on page 189 were deleted.

3. The following paragraphs were added to Comments on Page 189 after line 12:

Secretaries of State and all state officials responsible for drivers licenses should be encouraged to print on the back of drivers license language permitting the individual to make a gift of all or specific parts of his or her body on death pursuant to the law of that state.

(Sample forms for use on drivers license currently in use in Wisconsin and Michigan were added to the Comments.)

More comprehensive forms for the anatomical gift by a living donor or by the next of kin or other authorized person are as follows:

PROPOSED UNIFORM ACTS FOR A STATUTORY WILL, STATUTORY TRUST AND STATUTORY SHORT FORM CLAUSES*

INTRODUCTION

In many parts of the country increasing consideration is being given to the concept that legislation can aid the legal profession and the public by providing the means to meet the estate planning needs of many persons with small to medium sized estates by simple, short, economical and competent instruments. There is widespread recognition that the estate planning process has become too complicated and too costly for many persons. There is also too much risk of error for many lawyers who, although called upon to provide the services, are often not experts in the drafting of wills and trusts. And the lawyer's task is becoming more and more risky under the increasing hazards imposed by tax legislation and malpractice litigation.

This committee is convinced that appropriate legislation can make a constructive contribution to a solution. Our committee has attempted to review relevant statutes that have been enacted and proposals made in states where consideration has reached that stage. We have solicited and had the benefit of comments and drafts from a number of individuals.

With this report we submit drafts of three proposed uniform acts: (1) Uniform Statutory Will Act,[1] (2) Uniform Statutory Custodianship Trusts Act[2] and (3) Uniform Short Form Clauses for Wills and Trusts Act.[3] The acts have been drafted for consideration either as a package or as separate acts. If considered as separate acts, it must be borne in mind that the first two acts draw on provisions provided in the third. With a view to adoption as uniform acts the attempt has been to make them compatible with the language and format of the Uniform Probate Code, treating the Uniform Probate Code, although not enacted generally, as providing hopefully a kind of common language.

All of the acts employ the legal advice of a statutory form of incorporation by reference. They enable a settlor or testator to adopt statutory provisions by a simple form of incorporation by reference.

1. UNIFORM STATUTORY WILL ACT

This is a proposal for what many have come to refer to as a "statutory will". However, the proposed act would not adopt a will form. There is widespread apprehension that the adoption of a statutory will form, which would lend itself to use without legal advice by purchase from a stationer, is likely to encourage dangerous misuse. This risk cannot be completely excluded under the proposed statute, nor even under present law without any

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*Report of Committee on Fiduciary Services for Small Estates and Conservatorships, Probate and Trust Division.

[1] *See* Appendix A *infra*.

[2] *See* Appendix B *infra*.

[3] *See* Appendix C *infra*.

APPENDIX I

SURVEY OF ORGAN DONATION PROCEDURES

STATE:______________________________

I.D.#:__________________

1a. Could you provide us with a copy of your state's Anatomical Gift Act? YES NO

1b. IF NO, could you provide us with the citation to the statute? YES NO

1c. IF NO, who would you suggest contacting for the statute citation? ______________________________

2a. Does your state have a legal definition of death? YES NO

2b. IF YES, does your state statute include brain death in its definition? YES NO

2c. IF YES, could you provide us with the citation or a copy of the statute? YES NO

3. Is brain death generally used as the standard for death? YES NO

4. Are specific criteria used to determine brain death? (for example, Harvard criteria) YES NO

5. Who generally makes the determination of death?

____

6. Are there any other persons legally capable of determining death? YES NO

PHYSICIAN
OTHER HOSPITAL PERSONNEL
CORONER
MEDICAL EXAMINER
UNDERTAKER
POLICE, SHERIFF

7. Does the state have a provision on the driver's license for organ donation? YES NO

8. Are organ donor cards distributed independently of the driver's license? YES NO

9. IF YES, how are the cards distributed?

HOSPITALS ______
MEDIA ______
NATIONAL KIDNEY FOUNDATION ______
LIONS EYE BANK ______
PUBLIC EDUCATION, SEMINARS ______
____________________ ______

10. Does your program provide education concerning the awareness of organ donation and its procedures to

THE GENERAL PUBLIC? YES NO
HOSPITAL PERSONNEL? YES NO
LAW ENFORCEMENT PERSONNEL? YES NO

DESCRIBE ______________________________

____

____

____

11a. How is it determined if a potential organ donor is carrying a card?

____

____

____

11b. For example, what action would police take at the scene of an accident to identify a potential donor?

____

____

____

11c. What action would medical personnel take to identify a potential donor, either an accident victim or a brain dead patient?

12a. If a card is not found, would next-of-kin be consulted concerning organ donation? YES NO

12b. IF YES, who generally would approach the family?

13a. If a card is found, is formal consent from next-of-kin also required? YES NO

13b. If a signed donor card is legally sufficient for removal of organs, why is consent required?

14. Is there any way of finding out how many people carry organ donor cards? YES NO

DESCRIBE:

NAME:

Special Communications

Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions

Part I

Roger W. Evans, PhD

• Increasingly, it is recognized that resources available to meet health care needs are limited. Recently, this has been evidenced by reductions in federally funded health care programs and the leveling off of research funds made available to the National Institutes of Health. The problem of severely constrained resources is likely to become more acute, given new medical technology and the high cost of medical care. It is now apparent that both resource allocation and resource-rationing decisions will become inevitable, since not all persons with catastrophic or complicated medical conditions will be able to benefit from medical technology. While the careful assessment of health care technology can conceivably increase the efficiency of the health care delivery system, the methods by which allocation and rationing decisions are made must be improved. In doing so, it will ultimately be essential for this society to come to grips with life and death issues in a manner to which it is not accustomed.

(*JAMA* 1983;249:2047-2053)

DISCUSSIONS regarding the high cost of medical care in increasing numbers now include commentaries on the possibility that the resources available for medical care must be allocated across medical care programs. While in the past, resources available for the medical needs of the nation have at least been perceived as unlimited, the appearance of numerous large and small medical technologies and their indiscriminate use among some physicians has thrust resource allocation decisions into the forefront.[1] It is questionable whether it will be possible, in the future, to redistribute to medical programs resources available for other purposes. For example, resources earmarked for defense could be reallocated to meet health care needs. Meanwhile, it is now obvious that the health care of the nation is being jeopardized in at least two ways, both of which have implications for resource allocation. First, resources available to health care programs for the needy and disadvantaged have been threatened by budget cuts or have already been reduced substantially. Second, funds available for health-related research are being subjected to budgetary reductions.

See also pp 1973 and 2073.

These cuts also may affect both public and private insurance programs. These actions have heralded a renewed concern over which groups of beneficiaries are likely to be adversely affected.[2] For example, it is possible that resource limitations and ad hoc rationing systems could threaten the benefits currently derived through Medicare for patients with end-stage renal disease (ESRD) and various categories of Medicaid beneficiaries.[3] Accompanying these developments have been decisions by private insurers to revise coverage policies. Recently, some major insurers have begun to consider the possibility of limiting coverage to only those situations in which a physician providing treatment has performed a given procedure, such as coronary artery bypass surgery, a specified number of times. Policy initiatives such as this certainly raise questions about how persons with catastrophic illnesses will be treated in the future. Will medical care be regionalized or will the current, relatively fragmented delivery system remain in place?[4]

In past months there has also been a substantial reduction in funds made available for health-related research. Iglehart,[5] in a review of the status of the National Institutes of Health (NIH), concluded that "the NIH seems destined to face bleaker real budgets in fiscal 1983 and beyond." Thus, biomedical research is being given a lower priority, and, consequently, it is reasonable to expect that in the long run, the health of the population will be adversely affected. For example, it is becoming increasingly difficult to earmark sufficient

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From the Health and Population Study Center, Battelle Human Affairs Research Centers, Seattle.

Reprint requests to Battelle Human Affairs Research Centers, 4000 NE 41st St, PO Box C-5395, Seattle, WA 98105 (Dr Evans).

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Table 1.—Life Expectancy at Birth According to Race and Sex, United States, Selected Years From 1900 Through 1978*

	Total, yr			White, yr			All Other, yr†		
	Both Sexes	M	F	Both Sexes	M	F	Both Sexes	M	F
1900‡	47.3	46.3	48.3	47.6	46.6	48.7	33.0	32.5	33.5
1950	68.2	65.6	71.1	69.1	66.5	72.2	60.8	59.1	62.9
1960	69.7	66.6	73.1	70.6	67.4	74.1	63.6	61.1	66.3
1970§	70.9	67.1	74.7	71.7	68.0	75.6	65.3	61.3	69.4
1975§	72.5	68.7	76.5	73.2	69.4	77.2	67.9	63.6	72.3
1976§	72.9	69.0	76.7	73.5	69.7	77.3	68.3	64.1	72.6
1977§	73.2	69.3	77.1	73.8	70.0	77.7	68.8	64.6	73.1
1978§	73.3	69.5	77.2	74.0	70.2	77.8	69.2	65.0	73.6

*Data from Department of Health and Human Services.[40]

†For 1900 through 1902, data for the "all other" category were for blacks only.

‡Death registration area only. The death registration area increased from ten states and the District of Columbia in 1900 to the coterminous United States in 1933.

§Excludes deaths of nonresidents in the United States.

resources for clinical trials, one of the major methods by which the efficacy and safety of new technological innovations are assessed.[9-12]

A picture is now beginning to emerge in which, in the future, resource constraints are likely to make allocation decisions inevitable.[13] Consequently, the tasks of both the clinician and policymaker are likely to become more difficult. For example, in the absence of formal resource allocation rules and the failure to test new health technology adequately and to assess its broader social implications completely, clinicians to an increasing degree find themselves being forced to confront problems that traditionally have been reserved for biomedical ethicists.[14-19] Unfortunately, clinicians are often ill prepared to deal with complex bioethical issues. Few clinicians have previously been asked to participate proactively in the allocation, let alone the rationing, of health care resources. Many would argue that, in principle, this activity represents a conflict of interest and is contrary to the Hippocratic oath.

Policymakers, perhaps surprisingly, seem to be equally inept at resolving ethical dilemmas. As described by myself and co-workers,[20] this was particularly true of the End-Stage Renal Disease Program, in which it was decided that in a country where resources appeared almost limitless, the ethical and moral dilemma of selecting patients for treatment, based on a perceived need to limit treatment, was resolved rather easily by making additional resources available to treat people with ESRD. In describing the process by which Medicare benefits were extended to ESRD patients, my co-workers and I concluded the following:

> The federal government appears to have been more concerned with ridding itself of the moral dilemma of indirectly deciding who could live and who would die in a country of almost unlimited resources. The easiest way to eradicate this problem was to treat everyone equally by making everyone eligible for the same benefits.

Today, it is now apparent that this decision has only staved off the inevitable—deciding which patients should be treated under public and private insurance programs. The prospect that such decisions may become inevitable raises a number of important medical, social, ethical, legal, and economic questions. To the surprise and chagrin of many, such decisions are not completely foreign to the medical profession.[21,22] Problems of medical triage and the treatment of patients in intensive care units (including neonatal intensive care) and other "high-cost" users of medical care raise similar questions.[23-33]

LIFE EXPECTANCY, CHRONICITY, DISABILITY, MEDICAL TECHNOLOGY, AND MEDICAL CARE COSTS

The reason that bioethical issues have emerged among the more predominant issues in medicine today becomes clear when one considers the increased prevalence of chronic disease, the changing age distribution of the population, notable increases in life expectancy, the increased prevalence of disability, the introduction and widespread availability of new medical technology, and the high cost of medical care. The interrelationships among these are obvious. For example, the longer people live, the greater the likelihood that they will exhibit chronic disease, have subsequent disability, make use of new and expensive medical technology, and, ultimately, fall into the category of high-cost users of medical care.[34-38]

Life Expectancy

The percentage of persons older than 65 years has steadily risen in all industrialized countries during the past century.[39] While the proportion of elderly persons in the United States has doubled since 1900, their numbers have increased sevenfold. Today, the life expectancy of males, regardless of race, is approximately 70 years and for females is 77 years.[40] The average life expectancy for both groups is about 71 years. Overall, males are expected to outlive their earlier (1900) counterparts by 22 years, and females, their counterparts by 29 years (Table 1). While the longevity of nonwhites lags behind whites, the gains achieved by nonwhites have been even more dramatic as minority life expectancy in this country has doubled.

The composition of the population is also changing. In 1950, 12.3 million persons in the United States, or 8.1% of the total population, were older than 65 years. By 1960, this group had grown to 16.6 million persons, or 9.2%. The number reached 23.5 million in 1977, an increase of 91.1% from 1950, and this figure represented 10.9% of the total population. It is now projected that the number of persons older than 65 years will be 31.8 million by the year 2000—12.2% of the total population and a 157% increase in 50 years.[40] As the population ages, chronic disease and disability are becoming increasingly visible problems. Chronic rather than acute diseases are now the most prevalent causes of death in industrial societies.[33,41]

Chronic Disease and Disability

Since the early 1900s, there has been a substantial decline in those infectious diseases that have proved to be so intractable in past years.[42] Heart attack, stroke, cancer, and leukemia are but a few of those retrogressive chronic diseases, often of slow insidious onset, that have replaced infections, viruses, and tubercular fatalities in the United States.

Given current available data

Table 2.—Distribution of Persons With Limitation of Activity Because of Chronic Conditions, According to Age and Degree of Limitation, United States, 1978*

	No. of Persons, in Thousands			%			
Age of Both Sexes, yr	Total Population	With Activity Limitation (in Major Activity)	With no Activity Limitation	Total Population	With Activity Limitation	Limitation in Major Activity	With no Activity Limitation
All ages	213,828	30,306 (22,596)	183,523	100.0	14.2	10.6	85.8
<17	[illegible]	[illegible] (1,17[illegible])	[illegible]	100.0	[illegible]	[illegible]	96.1
17-44	88,627	7,501 (4,621)	81,126	100.0	8.5	5.2	91.5
45-64	[illegible]	[illegible]	[illegible]	100.0	[illegible]	[illegible]	76.4
≥65	22,798	10,262 (8,738)	12,536	100.0	45.0	38.3	55.0

*Data from Givens.[46]

sources, it is difficult to estimate the *true* prevalence of chronic disease. Few population-based epidemiologic studies have been undertaken to estimate explicitly the prevalence of all chronic diseases.[43] The Framingham Heart Study represents but one exemplary population-based epidemiologic study of cardiovascular disease. Results of this study have shown the now apparent decline in the prevalence of cardiovascular disease.[38,44,45]

Other statistics on chronic disease that have been published by the National Center for Health Statistics are based on self-reported illness and disability in the Health Interview Study. These reports indicate that in the early years of life, only about six of 1,000 persons endure chronic conditions. During young adulthood (age 25 or so), the rate increases to 35, and by the fourth decade that figure has almost tripled to 100 persons of every 1,000. By age 65, this number has again doubled and then doubled yet another time after age 75, until almost 90% of all persons older than 90 years live with a chronic illness.[46] Again ignoring the age factor, it has at times been estimated that approximately 50% of the civilian population, excluding residents in institutions, have one chronic condition or more.[47] As for the number of chronic conditions per person, one study has shown this to be 2.2.[47]

It is currently estimated that 80% of health care resources in the United States, including facilities, services, and biomedical research, are now devoted to chronic disease.[38] During 1978, an estimated 10.3 million persons, or 45%, of the civilian population aged 65 years and older not residing in institutions were reported in health interviews to have some degree of activity limitation caused by chronic disease or impairment (Table 2).[46] Of these 10.3 million persons, fully 85.2% indicated that they were limited in or unable to carry on major activities, affecting their ability to work or manage a household.[46] The remainder were limited but not in major activity.

Ignoring the age factor, 30 million Americans (14% of the total population) were reported to have dysfunction caused by chronic diseases, and, of these, 23 million, or 74.6%, were limited in or unable to carry on major life activities, affecting their ability to work, manage a household, or attend school.[48]

Medical Technology

Over the years, medical technology has been most successful in dealing with infectious diseases. Thomas,[49,50] in his analysis of technology, notes that much of the technology germane to the treatment of infectious diseases "comes from a genuine understanding of disease mechanisms, and when it becomes available, it is relatively inexpensive, relatively simple, and relatively easy to deliver." This technology is exemplified by modern methods for immunization against diphtheria, pertussis, and the childhood virus diseases and the contemporary use of antibiotics and chemotherapy for bacterial infections.[51] Other examples cited by Thomas[49] include the treatment of endocrinologic disorders with appropriate hormones, the prevention of hemolytic disease of the newborn, and the treatment and prevention of various nutritional disorders.

Major technological advances, however, have been made specifically for treating incurable chronic diseases, many of which have varying implications for the level of functional ability patients are able to regain. Since many of these interventions do not cure disease, they are frequently referred to as "halfway technologies,"[49,50,51] and the extent to which a patient is able to cope and regain maximum function becomes all important. As described by Crane,[32] technological changes have affected the very character of illness, permitting the physician to have greater control over the process of dying and the timing of death. She also notes that in less obvious ways, improvements in medical technology have produced increasing levels of disability in western society.[32] Moreover, technology has permitted the survival of more or less severely disabled persons such as diabetics and infants with myelomeningocele who would otherwise have died.

It is now estimated that each year, hundreds—perhaps thousands—of new technologies enter the medical care system. These include drugs, procedures, devices, and instrumentation, all constituting preventative, diagnostic, and therapeutic tools.[53] Many of these technologies have undoubtedly contributed to the substantial improvement in the health status of the American people. Also, relief of pain, amelioration of symptoms, and rehabilitation now have become possible for many patients with diseases that cannot be successfully prevented or treated.[53] The benefits of medical technology, in some instances, have been found to be more apparent than real.[54] For example, various inefficacious procedures have been practiced and then abandoned in this country. These include gastric freezing for peptic ulcer, colectomy for epilepsy, hypogastric artery ligation for pelvic hemorrhage, sympathectomy for asthma, internal mammary artery ligation for coronary artery disease, adrenalectomy for essential hypertension, and wiring for aortic aneurysm.[51,56,57]

While efficacy and safety (that is, medical technology's medical benefits and risks) have traditionally been the primary focus of health technology assessment,[11,33,38-43] attention has begun to focus on other aspects of health care technology.[43,44] For example, on June 12, 1980, Patricia Roberts Harris, then secretary of the Department of Health and Human Services, announced that new health technologies must be evaluated not only on the basis of their medical efficacy and safety but also on the basis of their "social consequences" before "financing their wide distribution."[45] As noted by Knox,[45] the approach being suggested by Harris was even more comprehensive than that used by, for example, the Environmental Protection Agency in dealing with pesticides, the Food and Drug Administration in its treatment of pharmaceuticals, and the Occupational Safety and Health Administration's approach to carcinogens in the work place.[46-48] New health technology was to be evaluated concerning its cost-effectiveness, cost-benefit ratios, ethical implications, and "long-term effects on society." The all-encompassing intent of technology assessment has been characterized by Banta and Behney[49] as follows:

> Technology assessment is seen as a comprehensive form of policy research that examines short- and long-term social consequences (e.g., societal, economic, ethical, legal) of the application of technology. Technology assessment is an analysis of primarily social rather than technical issues, and is especially concerned with unintended, indirect, or delayed social impacts.

It is now becoming more evident that the assessment of any emerging or existing technology must, at least, include consideration of the following parameters: (1) the potential need for the procedure, device, instrument, or drug, (2) the relevant constraints on the availability of the technology (eg, absence of donor organs for transplantation, location of treatment facilities, shortage of trained personnel), (3) the cost-effectiveness–cost-benefits of the technology assessed in terms of both economic and social costs, including lives saved, (4) the legal issues pertaining to the adoption and availability of the technology, including risks associated with its use (eg, where will the technology be made available?; who is eligible to receive the technology?; what risks does the recipient incur in the use of the technology?), and (5) the ethical issues concerning the selection of recipients of the technology, the allocation of resources to health care programs, and individual patient rights to health care regardless of cost and availability. Failure to consider these issues will make it extraordinarily difficult to anticipate the long-term implications of any emerging or existing technology.[70-72]

Cost of Medical Care

In 1980, expenditures for medical care consumed 9.4% of the gross national product (GNP).[74] In this same year, health care spending increased by 15.2%, representing a moderate acceleration over the 12.5% increase during 1979. This figure is substantially higher than the 13.4% growth rate between 1978 and 1979 and is certainly much higher than the average of 12.2% annually over the period of 1965 to 1979.[74] Gross national product increases have averaged 9.2% per year for the same period. This substantially greater growth rate in the health care sector compared with the rest of the economy resulted in the health care share of the GNP rising from 6.1% in 1965 to the 9.4% level seen today. Between 1950 and 1978 alone, in the United States, total annual expenditures for health care and other forms of health-related activities increased 1,500%.[75] In 1950, medical care expenditures constituted 4.5% of the US gross GNP.

In analyzing these increased health expenditures, it is obvious that third-party payers have, in many respects, contributed to the rise in health care costs, primarily because they have traditionally placed few constraints on expenditures. In 1979, personal health care funds supplied by third parties amounted to $147.0 billion of the $217.9 billion in personal health expenditures, or 68%.[74] Federal, state, and local governments financed the largest portion of that amount—about 40% of the total. Private health insurance payments covered an additional 27% of personal health care. In 1980, private insurers, including Blue Cross and Blue Shield plans, commercial insurance companies, and independent plans, paid benefits amounting to $58.1 billion, or 27% of personal health care expenditures. In 1980, approximately 76% of the US population was covered by private hospital insurance.[74]

Often the cost of disability is ignored as a health-related factor. This is somewhat misleading, since every chronic disease requires a certain level of expenditure for medical care, but, at the same time, the person may be disabled and, consequently, draws on disability programs for various cash benefits. The total cost of illness should reflect not only actual medical treatment costs but the cost of services and other benefits the person receives because of his illness.[76-83]

Table 3 gives a complete breakdown of government expenditures for illness-tested welfare programs for fiscal year 1975.[84,85] As shown here, in 1975, cash payments to disabled persons under these public programs amounted to more than $23 billion. The growth of the disability program is also interesting. As noted by Stone,[84] disability benefits administered through the Social Security program, although smaller than retirement benefits in total dollar amount, are increasing at a much higher rate, and the number of disability beneficiaries is also growing faster than the number of retirement beneficiaries (Table 4). A close examination of the Supplemental Security Income program presents a similar picture—federal payments to disabled persons grew by 18.6% between 1977 and 1980, as compared with an increase of only 8.0% in payments to the aged (Table 5).

The rapidly rising costs of health care have served to spur interest in health care technology assessment.[31,33,85-90] Recently, much blame has been placed on health care technology as the "culprit" behind high health care costs.[88,91,91-100] Although the total contribution of new technology to rising costs is controversial, estimates of the effect of technology on increased per diem hospital costs range from 33% to 75%, with 50% being an average figure.[31,54,88,101-103] Detailed case studies have been undertaken that illustrate the variable effect of technology on the treatment of chronic disease.[34] Scitovsky and McCall,[104] for example, looked at the changing cost of treating 11 different conditions at the Palo Alto Medical Clinic in California during a period of several years.[104] They found the real cost of treating five conditions fell, while the cost of treating six actually

Table 3.—Government Expenditures for Means-Tested Welfare Programs for Fiscal Year 1975*

Program	Amount, in Billion Dollars		
	Federal	State-Local	Total
Disability insurance (Social Security Administration)	7.6	. . .	7.6
Civil service disability	1.4	. . .	1.4
Railroad disability	0.2	. . .	0.2
Black lung benefits	0.9	. . .	0.9
Uniform services			
Veterans Administration and military disability	4.7	. . .	4.7
Other (income-tested)	0.5	. . .	0.5
Temporary disability insurance	. . .	0.9	0.9
Workman's compensation	1.3	3.2	4.5
Public assistance			
Supplemental Security Income—disabled	2.3	. . .	2.3
Aid to families with dependent children (disabled male head of household)	0.6	. . .	0.6
Total			$23.2†

*Data from Stone[illegible] and Skolnik and Dales.[illegible]

†Total does not include payments made through various private insurance arrangements or payments made for medical services.

Table 4.—Growth of Disability and Retirement Programs Under Old Age, Survivors, Disability, and Health Insurance, 1965 Through 1979*

Program	No. of Beneficiaries, in Millions		% of Increase	Amount of Benefits, in Billion Dollars		% of Increase
	1965	1979		1965	1979	
Retirement	13.9	22.4	61	12.5	59.3	374
Disability	1.7	4.8	182	1.6	12.6	691

*Data from the Department of Commerce, Bureau of the Census.[illegible]

Table 5.—Growth of Expenditures Under Supplemental Security Income, 1979 and 1980*

	Federal Payments, in Billion Dollars		% of Increase
	1979	1980	
Aged	2.5	2.7	8.0
Disabled	4.4	5.0	13.6

*Data from the Department of Commerce, Bureau of the Census.[illegible]

Table 6.—Growth in the Medical Technology Industry*

	1958	1977
Sales, billion dollars	1.0	8.1
No. of companies	[illegible]	[illegible]
No. of establishments	2,802	3,208

*Data from Wenchel.[illegible]

increased. Closer examination of these six conditions showed that there had been a notable increase in the use of diagnostic tests and therapeutic procedures per diagnosis. Laboratory tests per case of perforated appendicitis rose from 5.3 in 1951, to 14.5 in 1964, to 31.0 in 1971. Inhalation-therapy procedures for myocardial infarction rose from 12.8 per case in 1964 to 37.5 in 1971.[illegible]

Fineberg and Hiatt[illegible] have noted that, for several reasons, rising medical costs can be attributed to technology. First, although the trend is toward shorter hospital stays, this is accompanied by an increased consumption of resources during hospitalization. Second, more advanced equipment design may improve efficiency, but, with increased use of the equipment and other "induced costs," potential savings are never realized. Third, many new technologies do more than simply perform old services more efficiently—they provide new and expensive services. The intensive care unit, for example, is but a single innovation that in 1974 was found to account for 10% of all hospital costs.[illegible]

It is often argued that big, expensive technologies contribute disproportionately to the high cost of medical care, although the costs and benefits of a new technology largely depend on how and to which patients it is applied.[illegible] Moloney and Rogers,[illegible] however, have argued that the big and highly visible technologies such as the computed tomographic scanner "actually account for far less of the annual growth in medical expenditures than do the collective expense of thousands of small tests and procedures that are more frequently used by physicians and that individually cost little."

The use of a technology is directly related to reimbursement for its use.[illegible] Moloney and Rogers[illegible] suggest that one approach, although problematic, to slowing the use of a technology is to develop protocols" that instruct physicians to use technologies only when less expensive methods cannot provide adequate information on patient care; limit reimbursement to use according to these standards." At present, policies with regard to the reimbursement of new technologies, if they exist, are often inconsistent. Under the Medicare program, the major reason for excluding a technology for reimbursement is when it has not been demonstrated to be safe and effective.[illegible] As described by Bunker and associates,[illegible] "the government's reimbursement policy has been left largely to the commercial and nonprofit carriers to whom the government, by contract, has delegated the responsibility for processing claims." To accomplish this objective, some carriers, such as California and Massachusetts Blue Shield, have organized their own technology assessment committees and procedures. California Blue Shield has only recently placed limitations on procedures that are considered experimental. Previously, the carrier was committed to reimbursing for services that were "reasonable and necessary."[illegible] At present, there seems to be no satisfactory uniformly applied approach to limiting the growth of technology through alternative reimbursement policies.

Controlling the growth and distribution of technology is complicated by the fact that the medical technology industry is large and multinational.[illegible] To slow its growth through regulation surely would have a multitude of political ramifications. Since World War II, the medical technology industry has experienced dramatic growth in sales, firms, and establishments (Table 6).[111] Wenchel[111] attributes much of the growth to the increased demand for health services supported by private, voluntary health insurance and government programs such as Medicare and Medicaid, Hill-Burton, and Regional Medical Programs. The roentgenography and electromedical industries have seen the greatest increase in sales, showing an increase of $1.8 billion between 1958 and 1977.[113] Consequently, it is difficult to imagine that the medical technology industry is willing to sit idle as new regulations are introduced to slow the growth of technology. Perhaps this is most true in those situations in which existing rather than emerging technologies are being scrutinized.

SUMMARY

The foregoing discussion points to several problems and developments that indicate the inevitability of resource allocations to health care programs. The US population is aging; chronic disease is becoming more prevalent, disability a common occurrence. To meet the needs of an aging, chronically ill, and disabled population, a complex array of expensive and sophisticated medical technologies has emerged. The cost of these technologies will make it necessary to develop elaborate plans not only to enable them to be used but to ensure that people receiving them derive the maximum expected benefits. Thus, it is apparent that resource allocation decisions are likely not only to become a necessity but to become routine.[114,115]

In short, in the future, the demand for health care will doubtlessly outstrip available resources.[116,117] The problem then becomes one of determining how best to allocate the available resources to optimize the health of the population. To accomplish this objective, it will be necessary to study carefully new and existing technology to determine the magnitude of potential benefits.[10,11,51,56] At the same time, it will be necessary to increase the efficiency of the existing health care delivery system in an attempt to ensure that maximum benefits are being derived.[118] During this process, it is probable that some types of medical care can no longer be provided, or, if provided, they will be done so on a limited basis, since the derived benefits are too costly for all to benefit. The question then becomes one of determining the best method of implementing allocation decisions.[103,119] In doing this, it subsequently will become necessary to ration care within health care programs that have been spared from complete extinction. Although advanced technology will provide many persons with a new lease on life, not all are expected to benefit equally, if at all. As these allocation and rationing exercises are undertaken, a new appreciation of medical ethics will come about, accompanied by a more careful assessment of the nature of death and dying within this society.[121,122] These issues as they apply to this analysis are more completely delineated in part II.

This is part I of a two-part article. Part II will appear in the April 22/29 issue.

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Special Communications

Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions

Part II

Roger W. Evans, PhD

ALLOCATION AND RATIONING OF HEALTH CARE RESOURCES

Of all the resource-shortage crises this nation is expected to confront in the future, the problem of resource distribution is likely to be most acute and problematic in medicine.[21,30,123] Persons will be recognized as in need of, and then denied, benefits that the medical care provision system is capable of providing. Instead of an unidentified mass of persons being denied access to a needed resource, persons whose names have become known to the public will be declared ineligible for a treatment or service they are known to require.[124] Perhaps this scenario is inhumane, but it is undoubtedly a true representation of reality. As already noted, technology now permits to be saved the lives of persons who less than a decade ago would have surely died. Moreover, technology has made it exceedingly difficult to specify at precisely what point life ceases. This has prompted Crane[22] to conclude that both medicine and law are moving toward a "social interpretation" of life.

See also pp 2220 and 2223.

It should come as no surprise that the resources available to meet the demand for health care are limited.[125-130] Weinstein and Stason,[127] for example, have pointed out that decisions are already being made—physicians allocate their time, hospitals ration beds, fiscal intermediaries devise reimbursement policies—all of which suggest that priorities are being set. This is not to deny the recency of problems associated with resource constraints. Even a few decades ago, before the proliferation of medical technology and the pervasiveness of insurance, constraints on health care resources were largely unheard of. In the past, the distribution of health care resources has been accomplished by implicitly limiting their availability or, when available, restricting people's access to them.[131] Thus, the concepts of availability and accessibility are critical to the problem of resource distribution.[132,133] *Rationing* is the term often used to describe the process of differentially distributing resources. *Rationing* has become a value-laden term—one that implies that persons are likely to be treated unequally.[134] *Allocation* is another term often used to describe the unequal distribution of resources. While *Webster's New World Dictionary* defines *rationing* as "a fixed portion; share; allowance," *allocation* is to "set apart for a specific purpose, to distribute according to a plan."

As suggested by the definitions of rationing and allocation, there is merit in distinguishing between the allocation and the rationing of health care resources. Others have used the terms *macroallocation* and *microallocation* to make a similar distinction.[134,135] Regardless of the terms used, it should be recognized that allocation and rationing differ with regard to temporality and level. First, allocation decisions are likely to precede rationing decisions. Second, allocation is a concept that does not apply well at the level of the individual patient but rather is more appropriately applied at the aggregate or health care program level.

In a period when resources available for health care have become increasingly constrained, attention is directed toward making the provision of health care more efficient. For example, although much attention has recently focused on the enormous cost of the End-Stage Renal Disease Program, the question being addressed is not whether patients should have their Medicare benefits cut off but rather how treatment can be provided at less cost. (The total cost of the kidney program in fiscal year 1982 is expected to be $1.8 billion. Stated in other terms, patients with end-stage renal disease [ESRD], representing <0.25% of all Medicare part B beneficiaries, now account for >9% of total Medicare part B expenditures.[136]) Thus, the debate over which type of therapy (primarily home or in-center dialysis) is least costly is again being hotly debated.[137-147] At the same time, there is renewed interest in methods by which donor organ availability can be increased.[148-151] Recent hearings once again have indicated that home dialysis is probably less costly than in-center dialysis but that kidney transplantation is a greater bargain since the cost is not only lower in the long run, but the quality of life of renal transplant recipients is generally thought to be better than that of patients receiving dialysis.[152-155] Since there seems to be room for improving the provision of ESRD services, there is only minimal consideration being given to reduction or discontinuation

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of benefits that patients with renal disease currently receive. Thus, resources will continue to be allocated to the End-Stage Renal Disease Program, but, in the future, greater attention will focus on the *intraprogram* allocation of resources. It will be expected that the agency responsible for administering the program, the Health Care Financing Administration (HCFA), will write regulations that will maximize the use of those resources made available to the program; that is, the HCFA will be expected to promote the least costly treatment modalities by providing incentives for their adoption.[138]

Should the resources available for health care become increasingly constrained, the Department of Health and Human Services will be put in a position wherein *interprogram* allocation decisions will become necessary. These allocation decisions would concern how to distribute resources across health and, perhaps, social and other publicly financed programs. For example, a question might be raised as to whether the resources currently used to treat kidney disease might better be allocated to prevention activities or to a maternal and child health care program in which the derived benefits are likely to surpass those currently received by patients with ESRD.[33] In the future, competition for the available resources is likely to be great. The high cost of some new technologies might well make their widespead use prohibitive. Should this prove to be the case, it will then be necessary to consider the rationing of resources within health care programs.

Resources are rationed at the individual level, while allocation occurs at the aggregate level. Once it is apparent that all who are in need cannot be treated, the question then becomes one of which potential recipients are going to derive the greatest benefits. Again, this is precisely what occurred during the early years of dialysis, when there was substantial patient selection by physicians or committees. At that time, it was decided that although all patients with ESRD had a terminal condition, some had better prospects for treatment than others.[30,116] The preferred candidates were selected on the basis of a variety of criteria, eg, age, medical suitability, mental acuity, family involvement, criminal record, economic status (income, net worth), employment record, availability of transportation, willingness to cooperate in the treatment regimen, likelihood of vocational rehabilitation, psychiatric status, marital status, educational background, occupation, and future potential.[30,136-138] These criteria served as the basis on which scarce resources were rationed. Similar criteria currently are used to select potential heart transplant recipients and, thus, also serve as a rationing mechanism.[139-143] The decision to extend Medicare benefits to patients with ESRD resolved the rationing problem for the federal government. However, as noted by myself and associates,[30] the federal government "appears to have been more concerned with ridding itself of the moral dilemma of indirectly deciding who could live and who would die in a country of almost unlimited resources" than with simply trying to deal with the more general problem of costly medical care.

Now that the federal government is at least willing to entertain the possibility of differentially allocating resources to health care programs, it inevitably will also have to entertain the need to ration health care resources once interprogram allocation has occurred and the efficient use of available resources is maximized. Should resources be constrained further and no greater efficiency attained, it would become necessary to ration the available resources to certain persons based on some uniform set of guidelines.

The foregoing raises two important questions that have yet to be addressed—(1) On what basis will resource allocation decisions be made? (2) How are criteria for rationing likely to be developed?

ESTABLISHING CRITERIA FOR EXPLICIT RESOURCE ALLOCATION

In the medical literature, one increasingly finds medical procedures, practices, and technology subjected to what is commonly referred to as "cost-effectiveness and cost-benefit analysis."[29,31,136-138,143-167] Although the two are related, they are different approaches to the assessment of health practices and technology. Nevertheless, both cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) are presented as tools that can be used by the policymaker to make resource allocation decisions.

A CBA or a benefit-cost analysis requires that both costs and benefits be assigned monetary values.[166] Various methods have been proposed to measure the resource value of health care benefits. These include, for example, expected productivity loss based on discounted future earnings at the age of death or disability.[82,169,170] The benefit-cost framework thus converts decreased deaths and disability into increases in productivity and treats them as the indirect benefits of a health intervention. Thus, indirect benefits are then combined with any direct savings in health resource consumption (the direct benefits) to yield a net value.

A CEA, unlike a CBA, does not require that both costs and benefits be assessed in monetary terms. Instead, the aim of a CEA is to measure benefits in nonmonetary terms using mortality, morbidity, or quality-adjusted life years. To this extent, a CEA preserves a sense of intangible health care benefits, whereas a CBA typically notes these but fails to assess them.[168] A CEA is particularly useful for comparing alternative approaches with the treatment of a given medical condition. For example, in-center hemodialysis, home hemodialysis, continuous ambulatory peritoneal dialysis, and kidney transplantation all represent alternative approaches to the treatment of ESRD. A CEA allows one to compare these treatments to determine which provides the greatest benefits at the least cost.[170] Similarly, heart transplantation might be compared with its alternative—traditional medical and surgical management—as approaches to the treatment of end-stage cardiac disease (ESCD).[30] Finally, percutaneous transluminal coronary angioplasty might be compared with coronary artery bypass surgery as alternative approaches to the treatment of atherosclerosis.[171,172] In all these instances, the goal of a CEA is the same—to determine which treatment approach to a given condition yields the greatest benefits at the least cost.

Both CEA and CBA can be applied on a larger scale than described herein. This application is critical to both intraprogram and interprogram allo-

Table 7.—Applying Cost-effectiveness and Cost-Benefit Analysis to Program Allocation Decisions

Type of Decision Required	Cost-effectiveness Analysis (CEA)	Cost-Benefit Analysis (CBA)	Method of Choice
Intraprogram allocation decision	Yes	Yes	CEA
Interprogram health allocation decision	Yes	Yes	CEA
Interprogram health *v* other publicly financed program allocation decision	No	Yes	CBA

cation decisions. A CEA can be used to compare the benefits derived from various health care programs to determine which program (not specific treatment approach) yields the greatest benefit at the least cost, provided the benefits of each program being compared are expressed in the same terms (M. C. Weinstein, PhD, written communication, April 14, 1982). For example, kidney dialysis can be compared with heart transplantation to see which has the greatest benefits, with benefits expressed in terms of mortality, morbidity, or quality-adjusted life years. Weinstein describes this process as follows:

> The comparison of cost-effectiveness ratios serves as a basis for allocating resources if the objective is to maximize health benefits. Thus, if kidney dialysis has a cost-effectiveness ratio (relative to the next best alternative for ESRD) of $60,000 per quality-adjusted life year, and cardiac transplant has a cost-effectiveness ratio (relative to the next best alternative) for ESCD) of $50,000 per quality-adjusted life year, then resources should be allocated to the latter ahead of the former.

In this case, the proposed interprogram analysis strictly applies to health care programs. Another pertinent example might be to compare the cost of a potential maternal and child health program with the End-Stage Renal Disease Program or a potential ESCD program.

If the goal of the interprogram analysis is to compare the expenditure of health care resources with other socially desirable uses of resources, such as a public assistance program, a cost-benefit analysis is appropriate. Within the CBA framework, all expenditures and benefits are converted to monetary terms, which permits direct comparisons to be made among various diverse programs. The results of such an analysis may indicate that resources should be reallocated from social and other publicly financed programs to support health programs and vice versa. The problem with the CBA framework, however, is the requirement that human lives and quality of life be valued in dollars.[117,127]

Ultimately, the major objective of an interprogram analysis that involves only health programs or health and other publicly financed programs is to ensure that those programs that produce the greatest benefit will be those that receive the greatest support from the federal government. In this regard, it is apparent that, given limited resources and a need to allocate them in the most effective manner possible, a CEA or a CBA allows programs to be ranked according to their effectiveness or benefits derived or both. Weinstein and Stason[127] have summarized how this is done in the case of CEA as follows:

> Alternative programs or services are then ranked from the lowest value of the cost-effectiveness ratio to the highest, and selected from the top until available resources are exhausted. The point on the priority list at which the available resources are exhausted, or at which society is no longer willing to pay the price for the benefits achieved, becomes society's cut-off level of permissible cost per unit effectiveness. Application of this procedure ensures that the maximum health benefit is realized, subject to whatever resource constraint is in effect.

Thus, it is now possible to see that the allocation of health care resources and resources available to other programs as well can be subjected to a formalized set of procedures. By requiring that all assumptions are cleary stated, it is possible to perform the necessary quantitative analyses required to make the appropriate allocation decisions. In those areas where the data are least secure, it is possible to undertake sensitivity analyses to explore further the impact of decisions under differing assumptions.

Table 7 summarizes which type of analysis can be applied to various allocation decisions. If possible to achieve, a CEA should be the method of choice. In only one instance is it likely that a CEA would be inappropriate. This is in the case wherein an interprogram analysis is required to compare health program expenditures and benefits with non-health-related program expenditures and benefits. In this case, it would be necessary to express in monetary terms the benefits derived from the program. If an intraprogram allocation decision is required, a CEA should always be the method of choice, while, in principle, both a CBA and CEA could be applied to making an interprogram *health* allocation decision.

ESTABLISHING CRITERIA FOR EXPLICIT RATIONING

The resource rationing problem is different from the resource allocation problem. Although, in many respects, allocation decisions set the parameters and constraints within which rationing occurs, it is somewhat more difficult to submit the rationing process to a formalized set of procedures. The literature on clinical decision making, although not solely intended to be a framework for rationing, does provide an excellent framework with which to view rationing.

Once resources have been allocated to programs, and should these not be sufficient to meet the demand of all in need, clinicians are left with the problem of deciding which patients to treat.[173-176] The problems that were faced in the early days of kidney dialysis already have been described, pointing to obvious problems with any system that basically discriminates among people in the distribution of health care resources.[177,178] According to many, all people have a "right to health care" and, in a country as wealthy as the United States, no one should go untreated.[179-185] Yet, people often fail to recognize that with every right there also is an obligation.[186,187] People have a responsibility, an obligation as it were, to care for themselves in a manner that will maximally ensure good health (eg, eat a good diet and exercise daily). Unfortunately, a vast majority of the population fails to fulfill its end of the "social contract" and chooses to engage in practices and behavior that are known to be detrimental to their health (eg, excessive smoking, drinking, eating, and failure to exercise). Therefore, it could be argued that if everyone has a right to health care, then appropriate contracts should be drawn up to ensure that everyone keeps their end of the bargain.[106] This, of course, would require regulatory reform and strict enforcement, something that would be difficult and costly to undertake. Ultimately, however, the limits of the broad humanistic concept of a right to health care must be recognized. Within the context of rationing, those persons who have done the most to preserve their health could conceivably be the first to benefit from the available resources.[107,108]

The problem grows in complexity when it is recognized that the final decision concerning the rationing of resources will be the shared responsibility of the clinician or medical team, the patient, and any other representative of the patient (eg, family or nearest of kin).[109] It is unlikely that explicit exclusion criteria will be developed that are equally palatable to all involved.[110,111] Thus, any criteria for rationing would be interpreted and practiced by individual clinicians.[110,104] This is consistent with the concept of the "clinical mentality" advanced by Freidson,[112] which suggests that clinicians see each patient as a special case and treat each accordingly. Medical practice is typically occupied with the problems of individuals rather than of aggregates or statistical units. To impose a set of rationing criteria that must be strictly adhered to implies that patients need not be considered as unique individuals but rather as aggregates. This would, in fact, represent a radical restructuring of the process of rendering clinical judgment.[106]

In the final analysis, it is possible to establish some general *guidelines* on, perhaps, a condition-by-condition basis, to be applied to decide whether a patient should be treated.[107] The problem, however, is that all cases will have to be reviewed individually, with explicit attention given to the manner in which each patient deviates from the guidelines. These decisions are likely to be made when any of the following conditions are met: (1) the treatment is determined to be futile, (2) the patient declines treatment, (3) the quality of the patient's life is unacceptable, or (4) the cost of providing care is too great.[107,108] In evaluating each case, what people decide to do will be subject to considerable variability. What is presented as a formal policy may be informally practiced in a variety of ways. Policy and practice can differ remarkably.

As described here, rationing is the process by which criteria are applied to selectively discriminate among patients who are eligible for resources that have been previously allocated to various programs. Rationing criteria, although conceivably developed at the aggregate level, are likely to be interpreted and implemented at the individual level. Thus, there are two major problems associated with rationing. These are (1) the development of acceptable criteria for withholding treatment on a condition-by-condition basis and (2) identifying that person or those persons who should make the decision not to treat.

Childress,[114] in his discussion of rationing, has distinguished between what he refers to as "rules of exclusion" and "rules of final selection." The first set of rules establishes the pool from which the final selections are made. The final selections are then based on the rules of final selection. Childress[114] provides the following advice: "The best approach to determining the pool for final selection is to forget that the resource is limited and to exclude only those patients whose medical and psychological condition would certainly prevent successful treatment." The rules for final selection, however, are more controversial. Major alternatives include social worth criteria or some form of chance (eg, randomization, lottery, or "first come, first treated"). Rescher,[115] pursuing this same line of thought, has suggested that there are two biomedical and three social factors relevant to final selection. Relative likelihood of successful treatment and life expectancy are the relevant biomedical factors, while the social factors include family role, potential future contributions, and past services. All of these criteria are difficult to quantify and evaluate.

At this point, it is again important to reiterate that the most critical decisions that must be confronted today are those involving the allocation of resources across health care programs.[117] Once these decisions have been made, it will then become important to consider whether rationing will be necessary and what form it will take. It is precisely at this point that the nature and requirements of clinical decision making will become increasingly subjected to public and professional scrutiny.[196-200] Furthermore, it is at this point that patients and their next of kin will become increasingly involved in the decision-making process, and quantity and quality of life trade-offs will become important.[174,201-203] The decision-making process is well described in the literature.[21,22,135,199,204-211]

RESOURCE ALLOCATION IN PERSPECTIVE

Most discussions of resource allocation and rationing are narrowly focused and lack perspective. Attention is often directed to how health care resources are spent and not how a reallocation of resources from other government programs, such as defense and other publicly financed programs, might produce considerable gains in the health status of the population. Take, for example, the controversy that currently surrounds the End-Stage Renal Disease Program. This program is obviously costly, and the benefits derived by many patients have been reported to be few.[20,211] Policymakers now question whether this program will be allowed to continue in its current form.[20,140]

Unfortunately, excessive attention has probably focused on the kidney program. The problems associated with providing medical care to patients with ESRD is only symptomatic of a more widespread problem—health care costs continue to escalate as a larger number of people increasingly benefit from new and expensive health care technology. However, it must be recognized that other health and social programs are equally costly. For example, in 1981, an estimated 100,000 to 125,000 Americans underwent coronary artery bypass surgery, first performed in 1968, and the numbers continue to rise.[212] Yet those who have the surgery amount to only 0.04% of the nation's population. At $2.0 billion per year (a conservative estimate according to Randal), coro-

Table 8.—Budget Authority by Function

Function (Budget Code)	Actual, in Billion Dollars, 1981	Estimates, in Billion Dollars					
		1982	1983	1984	1985	1986	1987
National defense (050)	182.4	218.9	263.0	291.0	336.0	374.9	408.4
Health (550)	66.9	75.2	77.8	81.4	93.6	110.7	126.6
Administration of justice (750)	4.3	4.3	4.5	4.6	4.5	4.6	4.6

Table 9.—Budget Outlays by Function

Function (Budget Code)	Actual, in Billion Dollars, 1981	Estimates, in Billion Dollars					
		1982	1983	1984	1985	1986	1987
National defense (050)	159.8	187.5	221.1	253.0	292.1	331.7	364.2
Health (550)	66.0	73.4	78.1	84.9	93.6	102.4	111.8
Administration of justice (750)	4.7	4.5	4.6	4.6	4.5	4.5	4.6

Table 10.—Conduct of Research and Development in Defense and Health*

Department or Agency	Obligations, in Billion Dollars			Outlays, in Billion Dollars		
	1981	1982	1983	1981	1982	1983
Defense and military functions	16.5	20.6	24.5	15.7	18.8	22.7
Health and human services	4.0	4.0	4.1	4.0	3.9	4.0

*Data from Iglehart.[7]

nary artery bypass surgery accounts for about 1.0% of the total annual US health bill.[214,215] The growth in the number of coronary artery bypass procedures performed each year has been substantial. In 1973, it was estimated that 38,000 such procedures were carried out in the United States at a cost in excess of $400 million.[11] Collectively, coronary artery bypass surgery is the most costly operation performed in this country and has boosted private health insurance premiums for the population as a whole.[211]

Interestingly, for most patients, the efficacy of coronary artery bypass surgery is questionable.[10,214-221] There is evidence that the procedure is effective in prolonging the life of patients who suffer from a major blockage of the main trunk of the left coronary artery, but evidence of the efficacy of the procedure on patients with "three-vessel disease" or in whom all three arteries are blocked is less clear. These patients presumably make up 30% to 40% of the total. Moreover, the rate of return to work among patients who have coronary artery bypass surgery is not impressive.[216,222-227]

The costs associated with neonatal intensive care are also high and are comparable with the costs of ESRD and coronary artery bypass surgery. A recent case study on the costs and effectiveness of neonatal intensive care estimates that the average expenditures per patient in 1978 were about $8,000, with costs for some patients well over $40,000.[228] Since there are no national data on the volume of neonatal intensive care being provided in the United States, only rough estimates can be produced, based on studies with small sample sizes and varying definitions of levels of care. Burdetti and associates provide the following estimates of neonatal intensive care supply and use:

1. Neonatal intensive care unit admissions—6% of all live births go to intensive care, accounting for 200,000 admissions each year.

2. Estimated average length of stay—eight to 18 days per patient.

3. Number of hospitals with neonatal intensive care units—600.

4. Number of intensive care beds—7,500.

5. Total cost of neonatal intensive care—$1.5 billion each year.

Thus, based on the foregoing, questions being asked about the treatment of patients with ESRD could also be asked of coronary artery bypass surgery and neonatal intensive care. Since Medicare finances only a small percentage of these procedures and services (perhaps 20.0% nationwide in the case of coronary artery bypass surgery, with Medicaid paying for another 5.0%), the amount of publicity they have attracted remains small. In the case of coronary artery bypass procedures, the majority of patients rely on third-party payers, but, even so, their out-of-pocket expenses may equal 20% of the total bill.[211]

To provide even greater perspective for this discussion, the current level of defense spending as well as expenditures associated with the federal corrections system should be examined. It is well recognized that the resources devoted to national defense dwarf those available to health and social programs.[229] It is less well recognized, however, that it now costs as much per year to support a convicted felon in the federal correctional system as it does to keep a person alive on home hemodialysis. It seems a paradox that producing and maintaining the means to destroy life and warehousing in correctional facilities people who have outright taken the lives of others continues to absorb enormous resources that might justifiably be used otherwise. Why is it that when health care programs are criticized as being too costly, no attempt is made to put this in perspective by looking at other, less desirable uses of resources?

Table 8 gives budget authority and Table 9 budget outlays as provided in the fiscal year 1983 budget of the US government.[229] National defense expenditures are more than twice those available for government-financed health care programs. The size of the budget for the administration of justice is minuscule when compared with either the budgets for national defense or health; yet, when one examines that portion of the justice budget devoted to corrections, it is not inconsequential, considering how the resources are used. In 1978, the average daily population in federal correctional facilities peaked at 29,347. Today, the average daily population has dropped to approximately 27,000. The cost per person per year (fiscal year 1981) for supporting persons convicted of violating federal laws as well as persons charged with crimes and detained for trial or sentencing is approximately $13,000 ($352 million per year for 27,000 persons). Yet, as the prison population is declining, inflation is driving up the costs of operations to a point where outlays for operating correctional facilities are expected to be about $367 million in 1982 and $386 million in 1983.

Iglehart[7] has recently summarized the proposed budget (fiscal year 1983) for major federal departments and agencies. Figures for defense and military functions and those for health and human services are given in Table 10. In reviewing the total budget, Iglehart concluded that, insofar as research and development funds are concerned, "research in physics, engineering, and other fields with potential military and industrial applications fared considerably better than did medical research."

For fiscal year 1984, the Reagan administration has requested a National Institutes of Health (NIH) budget of $4.1 billion, representing an increase of $73 million, or 1.8% over last year's proposal. Once the projected 4.9% inflation rate for 1983 is considered, however, the NIH will end up losing this modest gain in terms of real dollars.

Not surprisingly, the Department of Defense (DOD) is expected to fare well in 1984. Since his election, President Reagan has increased annual outlays for the DOD by 33%, with plans to increase the DOD budget by another 14% in 1984. As of this date, the administration has requested $274 billion for the DOD, with some congressmen indicating that this figure will be reduced by at least $15 billion. Overall, despite pending cuts in the DOD budget, it is still expected to increase by 30.0%, reaching a total of $29 billion, or 65% of the total US budget for research and development.

In the final analysis, it is apparent that resources directed to health care programs and health-related activities are not excessive when compared with other publicly financed programs of somewhat dubious value.[12] At the same time, it is evident that some health care programs have been unjustly criticized when it is recognized that other medical procedures are equally as costly as those currently receiving careful scrutiny, such as the End-Stage Renal Disease Program. Thus, the following conclusion is unequivocal—resource allocation decisions must be viewed in perspective.

FACING THE INEVITABLE —DEATH AND DYING

As described previously, numerous ethical issues surround the allocation and rationing of health care resources. When not all will benefit, the dilemma becomes one of choosing who will. The ethical problems inherent in CBA and CEA are by no means resolved.[10,231] It is apparent, however, that should these procedures be applied to resource allocation decisions, this society will become acutely aware of mortality.[212-231]

Historically, within this society, there is a preoccupation with health, almost to the point where death is observed as the ultimate of all evil. Major social surveys of the population have continuously shown that health is highly valued.[236] Interestingly, however, it has become increasingly difficult to define the parameters of health. Even a person's need and ability to interact with others has been designated as "social health."[238-241] Perhaps this is because of the fact that the most commonly accepted definition of health is that provided in the Constitution of the World Health Organization,[242] which states that "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Consequently, at least three types of health are found in the literature—physical health, mental health, and social health. It is now difficult to determine what is and what is not health.

Preoccupation with health is obviously an unacknowledged preoccupation with death and, perhaps, the process of dying. While many people fear death, the overriding concern is with dying, ie, the process by which death comes about. For the most part, this society seems to be fully committed to the preservation of life at all costs, despite the quality of life the afflicted is likely to lead. It has only been in recent years that clinicians and the public have been willing to straightforwardly acknowledge and verbalize their concern with what might be called the "quantity v quality of life trade-off."* Accompanying this, of course, have been open discussions of the value of human life.[79,81,83,244-251] The uncertainty of what follows death has led many to eschew death in favor of living, regardless of the quality of their existence. Recent studies, however, show that persons, when faced with the prospect of a long-term chronic illness, are at least willing to consider the prospects of a shorter but higher quality of life.[178,204,252]

This in itself suggests that people have come to grips with the notion of death. Nevertheless, widely held religious beliefs and convictions would suggest that a large proportion of the population is unwilling to entertain the possibility of voluntary euthanasia or passive suicide as solutions to prolonged suffering.[215] Some religious groups would, in fact, consider life with catastrophic long-term illness an act of God and the illness a test of their religious conviction. In fact, they may believe that illness enhances their ability to demonstrate their religious faith to others in a testimonial fashion.

Over the years, technology has evolved to a point where the determination of death is increasingly problematic.[253-256] In fact, the new understanding of death is largely a consequence of technological advances in life-support systems. The President's Commission has now grappled with the problem of translating the current physiological understanding of death into acceptable statutory language. The Commission was also interested "in the dispute between 'whole brain' and 'higher brain' formulations of death and appraising currently used brain-based tests for death, which have become increasingly varied and sophisticated."[257] A set of guidelines has been established for the determination of death, but these are not accepted by all.[254,255,257]

Thus, the ability of technology to stave off premature death through a variety of means makes it increasingly likely that this society will be unable to fully come to grips with death in a manner that facilitates the withholding of treatment when the expected outcomes are negligible or counterindicative to the well-being of the patient and his or her next of kin. Surprisingly, however, there is considerable interest in hospice care in the United States, which, in effect, suggests that a decision to discontinue vigorous treatment is acceptable.[262-264] As described by Saunders,[264]

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*References 21, 22, 128, 156, 164, 173, 201-203, 210, 243.

"The hospice movement sets out to ensure that every person who can no longer benefit from the increasing complexity of the general hospital will have the support he and his family need. The whole family is the unit of care and should also be seen as part of the caring team." By most standards, the hospice concept is not a new innovation; it dates back to as early as 1893, when St Luke's Hospital was established in London.

Perhaps unfortunately, it is rarely the case that the similarity between hospice care and the voluntary withholding of treatment is recognized.[illegible] The parallel is close, yet it is currently argued that patients, under all circumstances, should receive every extraordinary means of care available to prolong life. Only when society is fully able to come to grips with death and dying is it likely that "policies and procedures for decisions not to treat" not only will be formulated but will also be followed. This period is likely to be hastened as financial constraints force the issue. Putting this in prespective, Manning[illegible] has stated:

> Somewhere along the way, consciously or unconsciously, explicitly or implicitly, society will have to make some basic decisions about the allocation of economic resources as between human beings of advanced years and those who are younger. . . . We have not begun to consider the violent social dislocation that would be brought about if a large fraction of the population were to be kept alive for significantly longer periods of time.

As noted previously, the problems that must be addressed are essentially ethical or, perhaps, ethical-legal.[illegible] New medical technology has not only dramatically changed the practice of medicine, but it has also raised a variety of issues with which clinicians are rather uncomfortable. The problem, however, is that these issues are relatively new and must be worked through carefully. Many of the issues surrounding the allocation and rationing of resources are almost metaphysical in nature. There is no clear-cut solution to the problems they instill for society. Ethics are relative to time, place, and, perhaps most importantly, culture. The anthropologist Ruth Benedict,[illegible] in describing the "cultural relativist" perspective on culture, made a profound observation. She stated:

> No man ever looks at the world with pristine eyes. He sees it edited by a definite set of customs and institutions and ways of thinking. Even in his philosophical probings he cannot go behind these stereotypes; his very concepts of the true and the false will still have reference to his particular traditional customs.

The cultural relativist perspective nicely summarizes the problems inherent in making resource allocation and rationing decisions. Even though based on explicit and hopefully rational criteria, any plan that is eventually adopted is certainly debatable from the perspectives of others. To adopt a set of criteria is to make a decision about limiting treatment. On the other hand, to treat all patients with a given disorder or within a given disease category, regardless of derived benefits, necessarily implies the withholding of treatment from patients with other disorders. The question is truly one of priorities. Data can be used to set priorities, but human judgment must be exercised to determine which priorities will hold.

The future is likely to be interesting. The conscious development of explicit allocation criteria, as a first step in the direction of wisely using limited resources, will be controversial. Questions must be raised as to how resources will be allocated not only to health programs but social programs as well. There are certainly many patients with diseases and esoteric medical conditions who could benefit from additional resource allocations. In 1972, it was decided that patients with ESRD would be eligible for Medicare benefits, yet there were and are many other patients with diseases and conditions who could have sustained the prolonged attention of government agencies.

Allocation issues will obviously be submitted to a complex sociopolitical decision-making process. Decisions can be made on the basis of allocation tools such as CEA or CBA, or a grim political battle could be waged between different lobbying groups, each representing the special interests of patients with specific diseases or conditions. In either case, the first decision will be as to which patient groups will receive support (ie, the resource allocation decision); then, as resources continue to dwindle, allocations will be made within programs and decisions will be made as to how clinicians *might* ration the limited resources made available to them. Increasingly, it is apparent that this scenario approximates the situation of the kidney disease program today. As already noted, people at all levels of government are concerned about the amount spent on the kidney program and are looking for ways to stretch what seems to be increasingly finite resources. In this regard, it could be stated that the "battle" has just begun and that the "war" is yet to be fought.

While the dilemmas created by resource allocation and rationing decisions are undeniable, it would seem that they have and will continue to provide an impetus for a reconsideration of the meaning of death and the essence of life. Reasonably acceptable criteria have been established for the determination of death, yet the very essence of life continues to be elusive. People do seem to be on the verge of seriously valuing thier lives, not only in terms of longevity but in terms of quality.[117,201,202]

Although Condorset envisioned that a "period must one day arrive when death will be nothing more than the effect either of extraordinary accidents, or the slow gradual decay of vital powers; and that the duration of the interval between the birth of man and his decay will have no assignable limit," Choron[212] has aptly pointed out that "the postponement of death is not a solution to the problem of the fear of death. . . . There still will remain the fear of dying prematurely."

In his treatise on death, Ernst Becker[214] shows that the fear of death is universal and that this fear "haunts the human animal like nothing else; it is a mainspring of human activity—activity designed largely to avoid the fatality of death, to overcome it by denying in some way that it is the final destiny of man." He argues that far too much effort is put into establishing immortality, in his words, into establishing a "formula for triumphing over life's limitations." People have failed to take life and its limitations seriously. He concludes his discourse, as follows, with a challenge for those who have used science to define the very essence of life:[214]

> The problem with all the scientific manipulators is that somehow they don't take

> life seriously enough; in this sense, all science is "bourgeois," an affair of bureaucrats. I think that taking life seriously means something such as this: that whatever man does on this planet has to be done in the lived truth of the terror of creation, of the grotesque, of the rumble of panic underneath everything. Otherwise it is false. Whatever is achieved must be achieved from within the subjective energies of creatures, without deadening, with the full exercise of passion, of vision, of pain, of fear, and of sorrow. How do we know that our part of the meaning of the universe might not be a rhythm in sorrow?

Had Becker devoted his attention to an analysis of the full implications of life-prolonging, advanced biomedical technology, it is difficult to speculate what he would have concluded. It is likely, however, that he would have concluded that western society has become too infatuated with the fear of death and has failed to realize the true essence and value of life, despite its length.

Comment

I have attempted to put modern technology into perspective by noting that technological innovation is in response to the demand created by the increased life expectancy and changing age distribution of the population and the increased prevalence of chronic disease and its concomitant disability. Increasingly, it is recognized that sophisticated medical technology, however, is not without its price. In recent years, it has been argued that technology has been a major contributor to rising health care costs in this country. Whether technology will continue to be viewed as the culprit behind rising health care costs is yet to be seen.

Efforts are now being made to control technology by a more thorough, comprehensive, and ongoing assessment of new, emerging, and existing technological innovations.[51,266-270] In this regard, Relman[62,271] has correctly argued that one effective method of moderating the cost of medical care, while improving its quality, is to initiate "a major new national program of support for the evaluation of medical procedures of all kinds." From his perspective, it is the cost of ignorance associated with medical technology that is too great, not medical progress. In Relman's words, "The cost culprit is not technology per se, but only technology that is ineffective, superfluous, or unsafe."[62(p557),276] In short, the goal of technological assessment should not be to curb the development of technologies but rather to provide the means for an unbiased evaluation of new technology before it becomes too widely diffused in practice. To meet this goal, Bunker and associates[10,11] have proposed the establishment of a private, nonprofit corporation for the collection, analysis, and dissemination of data on medical procedures and for the support of new clinical trials. The Institute for Health Care Evaluation, as they refer to it, would be intended to fill partially the void created by the abolition of the ill-fated National Center for Health Care Technology.[277] This Institute would have neither policy-making nor regulatory functions. At the present time, the HCFA has taken on an increasingly visible role in the assessment and regulation of new health care technology.[278] This role is evidenced by two generic types of policy decisions that the HCFA must make, namely, (1) coverage decisions—whether an item or service is one for which the program can pay—and (2) reimbursement decisions—how much is appropriate to pay for a covered item or service.

Despite Bunker's proposal for an Institute for Health Care Evaluation and the remarkable and noteworthy efforts of the Office of Technology Assessment, the foregoing discussion concludes that technological assessment, although likely to increase the efficiency of the health care provision system, will not be sufficient to wholly resolve impending budget constraints proposed by the Reagan administration. There are, indeed, limitations on the resources that can be allocated to health care programs, although some reallocation decisions would serve to stave off the inevitable. In preparation for the inevitable, plans must be made and techniques developed for the effective allocation and rationing of health care resources. Various suggestions have been offered as to how cost-effectiveness and cost-benefit analytic techniques can be applied to the making of intraprogram and interprogram *allocation* decisions. Clinical decision analysis, although imperfect, is offered as a possible approach to dealing with the resource *rationing* dilemma.

The increasingly apparent need to allocate and ration health care resources has led to a careful scrutiny of medical care costs. Health economists continue to point out that health care costs are almost out of control and that a major solution to this problem is to make the current service provision system more efficient through various competitive strategies, despite the fact that recent reports indicate that competition can have a negative impact on the quality of care patients receive.[279] Taking a differing viewpoint, other commentators have correctly pointed out that the health care industry, employing approximately 4.3 million workers, is the second largest industry in the United States and that reductions in health care through competition or other strategies would serve to displace a large number of persons in this industry.[280] The effect would be dramatic as displaced health care workers "would either displace others from their jobs or go on the welfare rolls. Either way one looks at it, a shrinkage of the health-care industry would create a ripple effect throughout our economy."[280] This has led Kolff to suggest that efforts to control health care costs through careful technology assessment "totally neglects the notion that we should move towards a service oriented economy instead of towards an industrial production directed economy" (W. J. Kolff, MD, PhD, written communication, Feb 22, 1983). He asks, "What are we to do with our unemployed? Unless we expand our 'services,' there is no solution."

The causes and cure of medical cost inflation are only partially understood and, thus, remain debatable. Jellinek and others,[280-281] however, believe that there are factors other than the "delivery of health care or the marketing of illness" that have led to increased spending in the health care sector. Jellinek[281] believes that the continued rise in health care expenditures is a result of increased alienation and depersonalization associated with post–World War II society. The response of society is to compensate by aggressive attention to the individual when he or she becomes ill. Jellinek[281] summarizes his position as follows:

> Societal willingness to support extraordinarily expensive new medical technology and advanced training, which implicitly communicates a willingness to place a high value on individual human life in contrast to the low value implied by industrial depersonalization, may represent one important form of adjustment of the social contract. The increase in society's expenditures for medical care may constitute a stabilizing force necessary to counter the destabilizing impulses generated by continued economic development.

In the final analysis, however, perhaps Jellinek's[illegible] assessment of the problem does not go far enough. For example, it seems almost a paradox that defense spending goes unchecked while, at the same time, massive cuts have been made in public health care assistance programs as well as health care research efforts. While public fund-raising efforts may produce the required resources to enable a young child to receive a liver transplant or a middle-aged person to obtain a heart transplant, to date, thee remains relatively little public debate over the merits of increased defense expenditures, which obviously pale current health care expenditures.

Unfortunately, the lay public, nevertheless, seems to be either unaware of or has chosen to ignore the key ethical issues implied by resource allocation and rationing decisions. Perhaps not uncharacteristically, people remain willing to come to the aid of identifiable victims of resource scarcity, such as persons in need of organ transplants. At the same time, the lay public finds a special attraction in persons such as artificial heart recipient Barney Clark, who has been honored for "risking his life in order to save it." Thus, in the end, perhaps, the real concern with personal health in today's society is not so much the depersonalization and alienation that many persons feel but rather the fact that destructive forces of an unprecedented magnitude have served to completely threaten human existence.[illegible] Consequently, for many people, the true value of life becomes most apparent either when a person's life is at stake because they are denied medical care that is available but in short supply or when the type of medical care required is unavailable. Although often highly publicized by the mass media, each of the patients who fall into these categories serves to underscore the basic dilemma—health care resources are limited.

The inevitability of resource allocation and rationing decisions has been well characterized by Fuchs.[125] In his discussion of the problems of health and medical care, he notes that an economic approach to these is firmly rooted in three fundamental observations of the world. These are as follows: (1) resources are scarce in relation to human wants, (2) resources have alternative uses, and (3) people have different wants, with considerable variation in the relative importance they attach to them. Yet, the basic economic problem identified by Fuchs[125] is "how to allocate scarce resources so as to best satisfy human wants."

While Fuchs places a great deal of emphasis on the economics of resource allocation and provides only cursory attention to the social, ethical, and legal implications of allocation and rationing decisions, the fact is that without economic constraints, most allocation and rationing decisions would be unnecessary except in situations in which the needed resource, natural or otherwise, is severely limited. In instances of the latter, economic resources would not be sufficient to alleviate scarcity. The basic premise of this discussion, therefore, is that constraints on economic resources will necessitate resource-allocation and rationing decisions, which, in turn, will make the confrontation of various social, ethical, and legal issues inescapable. In the future, the major issues confronting not only medicine but this society as a whole will be the social, ethical, and legal implications of resource allocation and rationing, whether framed in terms of distributive justice,[illegible] discrimination against the poor and disadvantaged,[illegible] or the withholding of treatment from those with catastrophic illness.[illegible] All of these share a common underlying theme—the need to confront human finality and purposeful existence.[illegible]

As described herein, the problems associated with the allocation and rationing of scare medical resources, economic (eg, health care dollars) or natural (eg, organs and tissue for transplantation) are, indeed, related to dying as an experience and death as an event. This discriminatory use of resources (and that is basically what allocation and rationing imply) has a lot to do with the fact that persons are eventually denied something they require—in this case, medical care. Schelling[126] underscores the essential ingredient of rationing decisions when he distinguishes between an "individual death/life" and a "statistical death/life." The two are, in reality, different and he provides the following example to illustrate his point:

> Let a 6-year old girl with brown hair need thousands of dollars for an operation that will prolong her life until Christmas, and the post office will be swamped with nickels and dimes to save her. But let it be reported that without a sales tax the hospital facilities of Massachusetts will deteriorate and cause a barely perceptable increase in preventable deaths—not many will drop a tear or reach for their checkbooks.

This distinction is an important one because it highlights the fact that the death of a person is a unique, often private event. Yet, at the local level, the victim and his or her family have an intense interest. In fact, as Schelling[126] notes, if society takes an interest in a local death, it is often because of a general concern that "reasonable efforts are made to conserve life than in whether those efforts succeed."

At this point in time, it is predictable that resource allocation decisions are unlikely to be carefully scrutinized by the public until resource rationing decisions become an inescapable fact of life. When the public is exposed to rationing decisions that it feels are contrary to the interest of the persons involved, despite catastrophic illness, it is likely to call into question the worthiness of allocation decisions. When it becomes apparent that these decisions are based on a mix of medical and social criteria, the latter which the public is much more likely to understand and despise as the basis for differentially valuing human life, the public will become increasingly irritated and resentful.

While selection criteria of any sort are likely to be viewed as unjust, it is a truism that not all people are likely to maximally or optimally benefit from available medical technology. For example, I and associates[illegible] have shown how dramatically the extension of Medicare benefits to patients with ESRD affected the composition of the patient population. In particular, indicia of patient rehabilitation, such as employment status, show a decline in the overall status of the patient population.

In the future, decisions must be made concerning which patients will maximally and optimally benefit from expensive health care technology, yet a watchful person must focus on such decisions to ensure that "social worth" will not be the criterion of final determination. The problem, however, is that, in many respects, social and medical criteria are inextricably intertwined. People of low socioeconomic status are likely to be in poorer health with multiple disease conditions, which, in part, reflects poor nutritional habits, detrimental lifestyle, and the historical lack of resources to obtain proper health care. Consequently, if medical criteria were to be the basis on which rationing decisions are made, they might exclude the poor and disadvantaged because health and socioeconomic status are highly interdependent. For example, it is not unusual to find that of those persons with ESRD, those of lower socioeconomic status are likely to have multiple comorbid health conditions such as diabetes, hepatitis, and hypertension. Not only are these patients less desirable candidates for dialysis and transplantation, but they are among the more expensive patients to treat.

Without careful planning and evaluation, the cleavage between the haves and have-nots, as evidenced by formal selection criteria, is likely to become substantial. Those with the financial means may be able to purchase the services they require, while those who are disadvantaged and destitute will be denied care. Claims of a right to health care might well serve as a common goal to bind the disenfranchised.[illegible] Specific laws have been promulgated to protect the rights of certain classes of persons; examples include Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act, and Title VII of the Civil Rights Act. Each of these laws has important implications for resource rationing decisions.

It is highly probable that disclosure of the names, by the media, of persons who have been denied the benefits of medicine will set into motion complex sociopolitical manuevering to reprieve those who have reportedly been treated unjustly by those with authority to make and enforce resource-rationing decisions. Arguments that surround these decisions are likely to be similar to those made in connection with abortion and the withholding of medical treatment.[illegible] The Quinlin, Saikewicz, and Dinnerstein cases will frequently be cited as precedent setting. Analogies are likely to be made between current events and the events that took place in Nazi Germany. To this end, it will be argued that to set forth criteria that deny people treatment, in effect, represents a devaluation of life. As Carroll[illegible] has noted:

> Life has become increasingly cheap in our time. Today, Auschwitz and Dachau are museums; Coventry, Dresden, and Hiroshima, vague memories; the deaths several years ago of hundreds of thousands of Indonesians, a footnote to history; race riots in American cities, a subject of study; and war casualties in Viet Nam, an object of routine reports.

Moreover, the practice of rationing will bring forth cries that the precedent is now set for the "floodgates to be opened" to the "mass slaughter" of persons whom rationing criteria declare to be of "marginal" value.

The point of the matter, however, is that rationing decisions are already being made.[127] The fact that they are not publicized has prevented them from becoming a social issue, despite the fact that they have attracted the attention of bioethicists.[21,22,307,308] Nevertheless, the future is likely to be filled with accounts of persons who have been refused treatment. Within a society that has failed to come to grips with the meaning of death and the essence of life, rationing decisions will seem unusually cruel. Yet, when these decisions are acknowledged as inescapable, this society, this culture, will be more prepared to deal with the one event that is truly inevitable—death.

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Mr. GORE. Thank you very much, Doctor.

Our final witness today is John McCabe, legal counsel to the National Conference of Commissioners on Uniform State Laws. Welcome.

Mr. McCABE. Thank you, Mr. Chairman.

I will make my testimony short because I think my position here mainly is at the invitation of the committee, to listen to what has transpired here and to ultimately take the committee's recommendations, so I can better advise my governing body with respect to any changes we may wish to make in the Uniform Anatomical Gift Act, or with respect to any other uniform acts that may be proposed.

We are the source of the Uniform Anatomical Gift Act and the Uniform Determination of Death Act, both of these acts we think having a significant impact or supposed to have significant impact upon organ donation and organ donation procedures. So, we have a significant interest in this area on behalf of State government.

We would be very hopeful that this committee would address its recommendations not only to the questions of Federal legislation, but to the questions of what might be applicable at the State level, what types of legislation, what types of legislative change ought to be made at the State level, knowing that that is frequently beyond the general concerns of committees of the Congress.

I say that because although we are an institution of State government, we are a very small body and a very under-resourced body. Your committee, with the people that it has brought before it and with the information that it is creating, has a much better opportunity to survey the issues and to come up with concise and, I would hope, comprehensive recommendations.

Beyond that, I would like to simply address a moment the legislative questions, it seems to me, that may arise in general with respect to changing or replacing the Uniform Anatomical Gift Act.

It is a bit of an irony, it seems to me, in a good deal of this. Going back to 1968, when we did the Anatomical Gift Act, we essentially extracted from a very confusing pattern of State statutory law and common law a voluntary system of organ donation.

Emphasis must be placed upon the voluntarism of the act. We created individual autonomy over the donation process over the decision not to donate, if that is what the individual decided to do.

Having done that, if there are now to be recommendations to somehow come back from that level of voluntarism, then I think we have a considerably different legislative task before us.

We have the task of coming up with appropriate language to deal with such things, presumably as presumptions, to opt out somehow enforceable choices to be made when people sign certain documents. We have those kinds of technical questions to address, but we also have considerable political questions to address.

The irony is that before 1968 we might have been able to do something with opt out or presumption when the law was a good deal more confused than it is now. But we have placed individual autonomy with respect to these decisions in the law in every State in the United States.

If we now go to the States and say we are going to change that, we must have a substantial record validating that decision and validating to the State legislatures—all 50 of them, plus the District of Columbia, plus Puerto Rico, plus the Virgin Islands, all of whom respond to my organization—reasons for those changes.

We must also come to them with a coalition of support, a significant enough consensus from the groups that support these issues, so that we can convince the State legislatures that the Anatomical Gift Act either needs to be significantly changed or needs to be replaced.

I am sure all of you have large collective legislative experience, clearly in this body and I suspect also in your own States. That is the general rule with regard to members of Congress. So you understand the problems of dealing with the 50 different state legislatures and the difficulties of the legislative process.

If there is to be change, if there is to be proposed change, we need two things: one, we have to have that coalition, we have to have that record to establish, to validate the reasons for change; and two, I think we have to stay as close to the voluntary approach as we can.

Thank you.

Mr. GORE. Thank you very much. That is quite helpful.

[The prepared statement of Mr. McCabe follows:]

STATEMENT OF JOHN M. MCCABE LEGISLATIVE DIRECTOR

National Conference of Commissioners on Uniform State Laws
645 North Michigan Avenue, Suite 510, Chicago, Illinois 60611 - (312) 321-9710

John M. McCabe
Legislative Director

April 5, 1983

Representative Albert Gore, Jr.
Chairman, Subcommittee on
Investigations and Oversight
Committee on Science and Technology
Suite 2321, Rayburn House Office Building
Washington, DC 20515

Dear Representative Gore:

I am pleased to represent the National Conference of Commissioners on Uniform State Laws (NCCUSL) before the Committee on Science and Technology on April 14, 1983, at the Committee's request. As I understand my role, from the letter of invitation and from discussions with the Committee staff, it is to monitor the Committee proceedings and to react to possible proposals for new state legislation on organ donation. The Committee's invitation was prompted by the historic impact of the Uniform Anatomical Gift Act, promulgated by the NCCUSL in 1968.

Insofar as I can fulfill that role, I shall be glad to do so. Certainly, I will be pleased to report the Committee's findings to the NCCUSL. However, I want to disclaim, initially, that I have any power to commit the NCCUSL to any position or to any action on any issue presented in these hearings.

As an initial matter, I would like to present a short summary of the developments leading to the promulgation and adoption of the Uniform Anatomical Gift Act. The NCCUSL records indicate that the first suggestions made to the NCCUSL for a Uniform Act pertaining to organ donation came from the National Pituitary Agency in 1965. After approval as a subject suitable for development as a Uniform Act, it was assigned to a Drafting Committee chaired by E. Blythe Stason, Professor and Dean Emeritus at the University of Michigan Law School. The records indicate that Dean Stason (now deceased) was a guiding force in the development of the Act. A first draft appeared in 1966.

The Drafting Committee activity soon received enormous input and support from the medical community. Drafts were widely circulated. The National Institute of Health provided advisors to the effort. In 1968, Dean Stason appeared before a subcommittee of the U.S. Senate, chaired by then Senator Mondale, to present the developing Act. All of these activities led to almost universal support for the Act from the medical and legal communities when the Act was promulgated in August, 1968. The Act received nearly simultaneous approval by the American Medical Association, for example.

The level of support was so great that the Act was uniformly adopted by every state except Kentucky by 1971. Kentucky joined the list of adopting states by at least 1977. In terms of achieving uniformity, this Act moved through the legislatures with great rapidity.

The Uniform Anatomical Gift Act has only one objective. It extracts from the confused character of the common law a definite power in each individual, by execution of a proper instrument, to donate parts of the body, after death, to medical institutions. The individual has complete autonomy in making any such donation, or in withdrawing it. Simplified forms are suggested, and, as the members of the Committee are probably aware, many states have incorporated the simplified forms into regularly issued documents, such as drivers' licenses.

It is important to recognize that the appeal of this Act was very much grounded in its voluntary character. Although drafted in the context of increased demand for transplantable organs, the Act's principal concern is individual autonomy over decisions made about the body after death. Many commentators believed, or hoped, that individual autonomy would increase the supply of transplantable organs, as people chose to execute donor instruments. If that hope has not been met, it must be remembered that the character of this Act made the supply of transplantable organs an implied and tertiary goal, from the beginning. And the problem of any change in the future will be that of subordinating individual autonomy, now clearly granted everywhere, to a primary goal of increasing the supply of transplantable organs. The political stakes will be far different from those wagered in the earlier effort to obtain and enact the Anatomical Gift Act.

Given that preliminary introduction to the Uniform Anatomical Gift Act, I would conclude by describing to the Committee the procedures of the NCCUSL for drafting a Uniform Act. The NCCUSL has a Standing Committee, called the Scope and Program Committee, that is responsible for considering subjects for new Uniform Acts and for considering amendments to existing Uniform Acts. The Scope and Program Committee reports its recommendations to the NCCUSL Executive Committee twice a year. If the Executive Committee approves drafting work, its recommendations must be approved by the NCCUSL membership at the Annual Meeting of the organization. Upon that approval, a Drafting Committee is appointed by the NCCUSL President. A Drafting Committee works a minimum of two years in preparing the proposed Act. Each Act must receive at least one preliminary reading and one final reading at an Annual Meeting. If the membership of the NCCUSL is satisfied with the draft at the final reading, it is subjected to a "vote by states." Each state's Uniform Law Commission caucuses on the promulgation of each Act. Each state has one vote. A majority of the states allows official promulgation of the Act. This is the sequence through which every official Uniform Act must pass.

Of course, official promulgation does not mean instant acceptance in the state legislatures. The NCCUSL proposes, but the state legislatures dispose. Achievement of uniformity, generally, requires a substantial coalition of groups supporting the same legislation. Hopefully, any legislative effort will not face a great deal of opposition, for opposition retards or prevents legislative enactment. If adequate support can be generated, uniformity becomes possible.

Having made these preliminary comments, I am at the Committee's disposal during the hearing on April 14.

Sincerely,

John M. McCabe
Legislative Director

JMM:cms

Mr. GORE. Dr. Wiecking, you were involved in legislation that was proposed in Virginia a few years ago to permit direct salvage of usable organs by medical examiners. This seems similar to what you testified has been enacted in some States. Yet in Virginia this recently generated an enormous public furor.

I have here a copy of an article from the Washington Post, referring to this as the "Harvest of the Dead" bill. Would you comment, please?

Dr. WIECKING. This was an attempt to permit the taking of a very small organ called the pituitary gland, and nothing else, deep inside the body. It was suggested by the pituitary-endocrine medical group because they needed to get the hormone to help dwarfs grow.

This was strongly opposed in the Virginia General Assembly by a certain religious group and by a libertarian group. Therefore, it was not enacted. In my opinion, if an obscure organ like the pituitary creates such a ruckus, I suspect it will be even more so with other, more visible organs.

Mr. GORE. This was only with respect to pituitary glands exposed during the process of autopsy. Is that correct?

Dr. WIECKING. Yes, sir.

Mr. GORE. And the public furor was enough to defeat that at the State level.

Dr. WIECKING. From two groups, yes, sir.

Mr. GORE. It was the American Civil Liberties Union and Orthodox Jews, correct?

Dr. WIECKING. Yes, sir.

Mr. GORE. Mr. McCabe, would there be problems with a mandatory checkoff as a halfway measure without going to a presumed consent? What do you think about that, a mandatory checkoff with a yes, no, undecided?

Mr. MCCABE. I would say something along those lines would probably more preferable, again, based on what we have now, which is a very voluntary system and a system which we created out of that early chaos of the common law. It wasn't clear before who owned the body and exactly what relationship that body had between the individual and society. There is not much doubt now. So, I think if you are going to tell the States that they are going to have to make a change, an incremental change, the less change that you can offer, the better chance you have of doing something with it.

It seems to me the checkoff system, or a system that provides less than the opt out type of system, might indeed have a better legislative chance, although it seems to me there are some critical questions to be addressed in that.

How do you enforce the checkoff system? What does it mean if an individual refuses to check off either yes, no, or maybe or whatever? How do you mandate that sort of thing in a way that will be acceptable, among others, to civil libertarians?

I think there are some questions with respect to that kind of an issue, too. Again, the closer you stay to the voluntary existing system, I think the better chance you have for doing something.

Mr. GORE. Dr. Evans, I understand that you have extensively examined the organ procurement agencies involved in obtaining organs, especially hearts, in addition to closely examining the current organ donation practices, which you have described.

You were also present during yesterday's hearings, and I am interested in whether or not you would agree with the characterization of the Nation's organ procurement effort that we heard yesterday. Do you think it can be made more efficient, more fair, more effective, more rational?

Dr. **Evans**. I certainly think that improvements can be made. I think the nice thing to see is that people are attempting to do that. The idea of expanding the Seopf system, the Southeastern Organ Procurement Foundation's computer network, is a realistic kind of thing which could be implemented on a larger scale.

Mr. **Gore**. You think that would be a productive step?

Dr. **Evans**. Indeed, I think that it would be a very productive step. Of course, as the problems were pointed out with extra-renal organs, there is a significant time problem in terms of how long that organ can be outside the human body. Provided major developments are made with regard to storage, a computerized system would become even more important.

Even given testimony yesterday and things that we have found, there is a fair amount of cooperation out there among the existing programs. There is room for improvement. I think everybody would acknowledge that.

Mr. **Gore**. Thank you very much.

Congressman Reid?

Mr. **Reid**. Chairman Gore, I have no questions.

Mr. **Gore**. It has been a long 2 days. We have one day remaining in these hearings, but it will not be until April 27. The Surgeon General and others from the Federal administrative agencies will testify at that time.

I would like to particularly thank the members of this final panel for their patience and indulgence. I would like to thank all of the witnesses that have appeared during these hearings.

We will stand adjourned until April 27, when we will take this matter up again in the third day of hearings. Thank you.

[Whereupon, at 1:30 p.m. the subcommittee adjourned, to reconvene Wednesday, April 27, 1983.]

ORGAN TRANSPLANTS

WEDNESDAY, APRIL 27, 1983

House of Representatives,
Committee on Science and Technology,
Subcommittee on Investigations and Oversight,
Washington, D.C.

The subcommittee met, pursuant to recess, at 9:35 a.m., in room 2325, Rayburn House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Present: Representatives Gore, Volkmer, Reid, and Skeen.

Mr. Gore. The subcommittee will come to order.

I would like to welcome all of our guests and witnesses. I have an opening statement, and then we will proceed with our first panel.

This morning the subcommittee continues its third and last in this series of scheduled hearings to evaluate the national system of obtaining and allocating human organs for transplant surgery.

At our opening session 2 weeks ago, the subcommittee heard compelling and at times heart-rending testimony describing the inadequacies of the effort nationwide to stimulate voluntary organ donation in order to obtain enough organs to meet the demands for this often life-saving surgery.

There was no more eloquent testimony explaining the problems we are examining here today than the statement of Mrs. Billie Hall, whose son Brandon underwent the first of two lengthy liver transplant procedures directly after the hearing. Mrs. Hall told us, "We have got ours. With God's help, we are going to make it. But there are so many here who might not."

The fact that Brandon Hall was able to obtain organs for two transplants in the past 2 weeks demonstrates that transplantable organs are available and that public and private programs must seek to improve donor awareness and establish better networks to link donors and those who will benefit from the surgery.

I might say, parenthetically, for those in the hearing room who were here when Mrs. Hall testified, that we got a brief update this morning on Brandon Hall's condition. It is listed as stable. I visited him Sunday, and he is improving right along, or appears to be. His doctors are the ones who should make any statement about that. But he certainly is doing quite well.

The condition of the second child in the same hospital, however, awaiting a transplant is now judged critical, and an urgent search for a liver donor is underway for that child.

We heard during the previous hearings about private sector efforts to enhance organ donation and to coordinate organ allocation. What is being done to enhance the collection of organs by the Federal Government? We will hear about some of these efforts today. There will, we hope, be some good news, but some questions will be raised as well.

For example, one Federal effort to enhance organ donation was conducted in Georgia hospitals in the late 1970's by the Centers for Disease Control. Over a 2½-year period, the CDC effected a dramatic, almost nine-fold, increase in usable kidneys retrieved.

This program was hailed by the AMA Council of Scientific Affairs, who urged support for its promotion and nationwide development. A proposal to expand the program and establish five demonstration projects was estimated to yield 500 additional kidneys per year, with an estimated cost savings of $25 million to $28 million for 3 years and $169 million to $200 million over 10 years.

Yet, we were informed that the CDC was forced to terminate this effort in 1979. What are the reasons for this? I hope today's witnesses from the Department of Health and Human Services can help to answer this question for us.

We also heard some very disturbing testimony during our previous 2 days of testimony. Witnesses told the subcommittee that potentially life-saving techniques, such as liver transplants, are simply not available to many because they are considered "experimental" and therefore not reimbursable under various government medical programs, both civilian and military.

It is not easy to forget—nor do we want to forget—the testimony of Capt. John Broderick about his 2-year-old daughter, Adriane, who could not get a much-needed liver transplant because the Army's medical insurance program, CHAMPUS, would not reimburse for the surgery.

The subcommittee has received numerous letters and pleas from others with stories as compelling and troubling as that of Captain Broderick and his daughter.

So, today, we will continue our examination of the programs established to obtain organs for transplant surgery, but we will also shift our focus somewhat and examine more closely why Captain Broderick has been unable to get the Army to pay for his daughter's transplant and why civilians coming under other Federal programs face similar hurdles. These are important questions because many private insurance carriers look to the Federal programs for guidance.

To get answers to our questions, we are privileged to have distinguished representatives from the two primary Federal agencies involved in these issues, the Department of Health and Human Services and the Department of Defense. We will be asking these agencies two principal questions. We will ask these questions primarily about liver transplants, but the questions have far broader implications.

The questions are: one, how does a new technology, such as liver transplants, go from being considered experimental and nonreimbursable to being efficacious and available to all, regardless of their ability to pay? No. 2, how can new life-saving techniques, which have been demonstrated to be effective, yet may still be considered experimental, be made available to those in need who cannot afford to pay for them?

We look forward to a lively discussion of these issues. Hopefully, there will be some progress toward achieving uniformity in delivery of such vital services and valuable suggestions to improved organ procurement and allocation.

I would like to recognize the ranking minority member of the subcommittee, Congressman Skeen.

Mr. **Skeen**. Thank you, Mr. Chairman.

I have no extensive opening statement. I just want to welcome the panel here. I think these discussions have been extremely significant, and I think they have contributed a great deal to the public view of what organ transplant technology is all about, the progress that has been made, and where do we go from here in deciding what are the ethics involved in this discussion.

I think, once again, that this has been a very significant series of hearings. I want to commend the chairman. But, particularly, I am interested in what today's witnesses have to say.

Thank you very much, Mr. Chairman. We will get into the testimony.

Mr. **Gore**. Thank you very much.

We are particularly honored that the distinguished individuals on this first panel have demonstrated their willingness to come and share in this effort.

Dr. Edward Brandt is Assistant Secretary for Health in the Department of Health and Human Services. Dr. Carolyne Davis is Administrator of HCFA in HHS. Of course, Dr. C. Everett Koop is the Surgeon General of the United States and Assistant Secretary for Health with the Public Health Service. Dr. John F. Beary, III, is acting Assistant Secretary of Defense for Health Affairs in DoD.

These witnesses are accompanied by, on the part of Dr. Davis, Dr. Donald Young, who is, I think, with you and will be prepared to answer questions if necessary. Dr. Beary is accompanied by Dr. Alexander Rodriguez, Medical Director of CHAMPUS, and Robert Gilliat, Assistant General Counsel for Manpower and Health Affairs with DoD.

In accordance with the wishes of the panel, we are going to recognize you in the following order: Dr. Brandt, Dr. Davis, Dr. Koop, and Dr. Beary.

Dr. Brandt, without objection, the entire text of your statement and those of the other witnesses will be included in the record in full during the hearings. If you care to summarize any portion of your statement, feel free to do so. If you wish to present it all, that is fine, too. Please proceed.

STATEMENT OF EDWARD N. BRANDT, JR., M.D., ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. **Brandt**. Thank you very much, Mr. Chairman. I will summarize my statement.

I would like to ask first if we could change the order briefly to have Dr. Koop follow me, since it fits right in and expands on a portion of my testimony.

Mr. **Gore**. Surely. That is, I think, most appropriate, and we will handle it precisely that way.

Dr. **Brandt**. Thank you, sir.

It is a pleasure to appear before you today to discuss the work of the Public Health Service in organ transplantation. The issues you have discussed in this set of hearings are important and have obvious life-saving implications.

In my testimony, I will describe for you the part the Public Health Service has played and continues to play in organ transplantation and related areas.

Much of the work of the Public Health Service deals with the development of new knowledge in the biomedical sciences to improve our understanding of disease: its progression, its treatment, and its prevention. This research is conducted mainly at the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration.

In addition, as you know, we have responsibility for assurance of public health and safety through the regulation of drugs and devices used in the diagnosis and treatment of disease. I shall discuss this aspect in more detail later in relation to Cyclosporin A, which is a new drug which has increased the efficacy of transplant surgery.

Third, the surveillance and prevention of public health problems are the responsibility of the Public Health Service, particularly the Centers for Disease Control.

Finally, when asked by the Health Care Financing Administration, we do assess the safety and efficacy of new procedures in order to help HCFA make coverage decisions.

The aim of our basic and clinical research is to develop procedures for the most effective selection of recipients of grafts; to develop optimal procedures to condition the recipient prior to transplantation in order to minimize the risk of rejection; to identify those factors that trigger the rejection of transplant; and to develop ways in which to prevent and treat rejections.

Highlights of the NIH research include the work on cyclosporin A which, although new, is reportedly much more effective than older immunosuppressant drugs. Additionally, NIH is funding research on multiple pre-transplant blood transfusions, which have been shown to enhance renal graft survival rates up to 60 percent, a significant prevention of early graft failure.

Furthermore, sufficient data and sophisticated analytic techniques are now available for renal and bone marrow transplantation to permit accurate identification and estimation of the relative importance of risk factors and therapeutic strategies. We can now predict probable outcomes for individual patients and for particular populations with those two grafts.

The accomplishments to date are promising. At least three transplantation procedures are established features of clinical practice today: cornea transplants, kidney transplants, and, for some conditions, bone marrow transplants.

While the use of cyclosporin A is reported to be of major importance in improving the survival of patients with kidney, liver, or heart transplants, we must recognize that the post-operative problems are very real. Whether children with liver transplants will grow normally, what survival rates after a year or two will be, what the long-term risks are with respect to cancer and repeated infections are all questions for the future.

We will need to rely on future research to address three very important problems. First, our knowledge of tissue typing remains incomplete. A second area requiring further study is the problem of rejection. Better drugs are clearly needed that can be targeted to specific immune systems rather than suppressing the entire immune system of the body.

Third, more work is needed in the area of organ preservation.

The state of the art in liver transplantation has been advancing so rapidly that data is only now beginning to evolve about the procedure. NIH has invited the leading researchers and practitioners in the field to share their data and experiences at a Consensus Development Conference on Liver Transplantation to be held in June of this year.

The purpose of this conference is to address the following questions:

Are there identifiable groups of patients for whom transplantation of the liver should be considered appropriate?

In terms of current survival rates, complications, and other outcome criteria, how do these various groups fare?

What are the principles guiding selection of the appropriate time for surgery in potential candidates for transplantation?

What are the skills, resources, and institutional support needed for liver transplantation?

And, what are the directions for future research?

The new immunosuppressant drug, cyclosporin A, has been used in combination with adrenal corticosteroids to prevent organ rejection in kidney, liver, and heart transplants. Initial review suggests that cyclosporin A has dramatically increased success rates of kidney and liver transplants, while modestly affecting the success of heart transplants.

The drug now is in the final stages of the review process for approval by the FDA.

As transplant science and technology efforts succeed, issues related to organ procurement and service delivery become more prominent. I believe you should know that the Public Health Service plays a role in the area of organ procurement as well.

The shortage of donated kidneys has not shocked the Nation's conscience because hemodialysis can keep patients alive while they await a transplant. However, the lack of a heart or liver for transplantation may mean death.

The Centers for Disease Control, as you pointed out, developed an approach to organ procurement using public health principles in order to demonstrate how to increase the number of organs procured, and their demonstration, Mr. Chairman, resulted in a threefold, rather than a ninefold, increase in the number of kidneys available for transplantation on an annual basis.

It was demonstrated that by applying a more systematic and timely approach to identifying potential donors, the number of organs actually procured could be increased. They developed a system involving a number of procedures which are detailed in the complete testimony.

The results of this demonstration have been widely disseminated in the professional literature, and the CDC has provided, and continues to provide, technical assistance to procurement centers interested in increasing organ availability.

Dr. Koop will sponsor a workshop in June to focus attention on the need and to explore measures to increase the availability of organs for transplantation.

The Office of Health Technology Assessment within the National Center for Health Services Research has been asked by HCFA to evaluate the safety and effectiveness of heart, pancreas, and liver transplants.

Public Health Service assessment of the heart transplant has been suspended until the Battelle Center National Heart Transplantation Study is completed in April and a report submitted in July.

In April of 1982, HCFA asked us to reassess liver transplantation. As is our usual practice, we published a notice in the Federal Register about our intent to evaluate these technologies and, at the same time, contacted appropriate Federal agencies, medical specialty societies, and health insurance and manufacturing associations.

With material from these sources, information that the NIH Consensus Development Conference on Liver Transplantation generates, and staff review of the literature, the Office of Health Technology Assessment will develop PHS recommendations regarding the safety and effectiveness of liver transplantation for usual circumstances in the practice of medicine for HCFA's use. The results of the liver assessment should be available sometime this summer.

Various agencies of the Public Health Service are active in trying to address many of the concerns voiced before this subcommittee. In describing our activities, I have outlined the role we play in research and drug regulation, in public health surveillance and conscience raising, and in technology assessment.

I can assure you that all of these efforts, including those to develop knowledge and explore new treatments, will continue in the hope that, ultimately, research will identify the cause and progression of these diseases, thus, in the future, preventing the need for organ transplantation.

[Prepared statement of Dr. Brandt follows:]

STATEMENT

by

EDWARD N. BRANDT, Jr., M.D.

ASSISTANT SECRETARY FOR HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to appear before you to discuss the work of the Public Health Service in organ transplantation. I am Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, Department of Health and Human Services. With me is Dr. C. Everett Koop, the Surgeon General of the Public Health Service. Dr. Carolyne Davis, Administrator of the Health Care Financing Administration (HCFA), will also be discussing the activities of her agency.

The issues you have discussed in this set of hearings are important and have obvious life saving implications. No one who has followed the hearings and the stories of Jamie Fiske and Brandon Hall can fail to be moved by the ordeal of children waiting for an organ transplant. In my testimony, I will describe for you the part the Public Health Service has played and continues to play in organ transplantation and related areas.

Much of the work of the Public Health Service (PHS) deals with the development of new knowledge in the biomedical sciences to improve our understanding of disease: its progression, its treatment, and its prevention. This research is conducted mainly at the National Institutes of Health (NIH) and the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA). In addition, we have responsibility for assurance of public health and safety through the regulation of the drugs and devices used in the diagnosis and treatment of diseases. As you know, the Food and Drug Administration is the principal agency responsible for this activity. I shall discuss this in more detail later in relation to Cyclosporin A, the new drug which has increased the efficacy of transplant surgery. Third, the surveillance and prevention of public health problems are the responsibility of the Centers for Disease Control (CDC). CDC has also made contributions to the area of organ transplantation as has the Office of the Surgeon General. Finally, when asked by HCFA, we assess the safety and effectiveness of new procedures in order to help HCFA make coverage decisions. The Office of Health Technology Assessment (OHTA) at the National Center for Health Services Research serves this function for the PHS.

The Development of New Knowledge

The National Institutes of Health supports basic research on transplantation as well as organ-specific research on the heart, heart and lungs, kidneys, liver, and pancreas. In addition, the NIH supports research on other transplantable tissues, including corneas, bone and cartilage, bone marrow, and skin. The aim of this basic and clinical research is to develop procedures for the most effective selection of recipients of grafts; to develop optimal procedures to condition the recipient prior to transplantation in order to minimize the risk of rejection; to identify the factors that trigger the rejection of transplants; and, to develop ways in which to prevent and treat rejection. We look to this research to increase our understanding of transplantation and to develop improved techniques of immunosuppression that will enhance graft survival and function, as well as reduce complications that lead to graft rejections.

The major NIH Institutes involved in organ transplantation research are the National Institute of Allergy and Infectious Diseases; the National Heart, Lung, and Blood Institute; and the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. In Fiscal Year 1982 these three Institutes combined supported approximately 230 projects at a funding level of about $36 million on organ transplantation research.

Highlights of the NIH research include the work done on Cyclosporin A, which, although relatively new, is reported to be much more effective than older immunosuppresive drugs in increasing survival rates in a wide variety of transplanted organs including the kidney, liver, and pancreas. Additionally, NIH is funding research on multiple pretransplant blood transfusions--shown to enhance renal graft survival rates up to 60 percent--a significant prevention of early graft failure.

Furthermore, sufficient data and sophisticated analytic techniques are now available for renal and bone marrow transplantation to accurately identify and estimate the relative importance of risk factors and therapeutic strategies. We can now predict probable outcomes for individual patients and for particular populations. Thus, more effective tools for patient counseling and for better informed and more objective allocation of public resources can be utilized.

The accomplishments to date are promising. At least three transplantation procedures are established features of clinical practice today--cornea and kidney transplants and, for some conditions, bone marrow transplants. In 1981, approximately 4,500 transplants of kidneys and 600 of corneas were performed. Advances in immunology and the experimental use of Cyclosporin A have extended the application of transplant technology to the heart, heart-lungs, the pancreas, and the liver. Over the past year, transplants of some 80 livers, and 10-15 pancreases, more than 100 heart transplants, and about 11 heart and lung transplants have been performed.

While the use of Cyclosporin A is reported to be of major importance in improving the survival of patients with kidney, liver, or heart transplants, we must recognize that the post-operative problems are very real. Whether children with liver transplants will grow normally, what survival rates after a year or so will be, what the long term risks are with respect to cancer and repeated infections are all questions for the future.

We will need to rely on future research to address three very important problems. First, our knowledge of tissue typing remains incomplete. This is especially so for certain minority populations for whom tissue typing techniques are still inadequate. A second area requiring further study is the problem of rejection. Our current armamentarium of drugs is not without threats of cancer and toxicity to the kidney. Better drugs are needed that can be targeted to specific immune systems rather than suppressing the entire immune system of the body. Consequently, we will be looking to basic research in molecular biology to explore the nature of cell surfaces and receptor sites for answers to these questions. Third, more work is needed in the area of organ preservation. Currently, hearts can only be preserved for up to 4 hours, livers for 10 hours, and kidneys for 72 hours. If techniques of organ preservation could be improved, the problems of organ availability could be greatly diminished. Answers to these questions could significantly affect the success of organ tranplantation.

The state-of-the-art in liver transplantation has been advancing so rapidly, that data is only now beginning to evolve about the procedure. NIH has invited the leading researchers and practitioners in the field to share their data and experiences at a Consensus Development Conference on Liver Transplantation to be held in June of this year. The purpose of the conference is to address the following questions:

- Are there identifiable groups of patients for whom transplantation of the liver should be considered appropriate therapy?
- In terms of current survival rates, complications, and other outcome criteria, how do these various groups fare?
- What are the principles guiding selection of the appropriate time for surgery in potential candidates for transplantation?
- What are the skills, resources, and institutional support needed for liver transplantation?
- What are the directions for future research?

Regulation of Drugs

As I mentioned earlier, the new immunosuppressant drug, Cyclosporin A, has been used in combination with adrenal corticosteroids to prevent organ rejection in kidney, liver, and heart transplants. Its usefulness in lung and pancreatic transplants is also being investigated. Initial review suggests that Cyclosporin A has dramatically increased success rates of kidney and liver transplants, while modestly affecting the success of heart transplants. Because of the promising results generated by clinical testing of the drug, the FDA has given it a high priority for review and the drug now is in the final stages of the review process.

On March 25, the FDA Oncologic Drug Advisory Committee recommended approval of the use of Cyclosporin A with adrenal corticosteroids. Subsequently, the sponsor has corresponded with the FDA regarding the application and discussions are now underway about certain technical issues.

Surveillance and Prevention of Public Health Problems

As transplant science and technology efforts succeed, issues related to organ procurement and service delivery become more prominent. In addition to supporting research and insuring safe and effective drugs, I believe you should know that the Public Health Service plays a role in the area of organ procurement as well. The shortage of donated kidneys has not shocked the nation's conscience because hemodialysis can keep patients alive while they await a transplant. However, the lack of a heart or liver for transplantation may mean death, resulting in desperate appeals by parents for livers, for example, without which their children would die.

The Centers for Disease Control (CDC) in the late 1970's developed an approach to organ procurement using public health principles in order to demonstrate how to increase the number of organs procured. This was done in response to the perceived cost-effectiveness of transplantation and the improved quality of life for transplant recipients, together with the shortage of cadaveric organs available for transplantation.

A study was initiated to assess the number of kidneys potentially available for transplant purposes. Medical records of deceased patients were reviewed using criteria developed by transplant surgeons for determining suitability of organ donors. These record reviews demonstrated that only a small proportion of suitable donors were actually being identified within the short time available to accomplish organ procurement.

It was also demonstrated that by applying a more systematic and timely approach to identifying potential donors, the number of organs actually procured could be increased. In a demonstration in Atlanta and Augusta, Georgia, CDC tripled the number of kidneys procured in a three-year period by implementing the following procedures:

- Instituting a procurement program in those hospitals which had been identified by record review as having potential donors.
- Making use of an existing operational procurement apparatus, consisting of surgeons, tissue typers, transplant coordinator, and the like.
- Establishing professional education to promote and maintain program visibility.
- Making daily visits to the hospital and the specific units to identify potential donors.
- Assessing the program's effectiveness by monitoring medical records to determine the number of potential donors and the number of donors actually being referred; to quickly identify where potential donors were being missed; and to understand the dynamics of the individual hospital.

The results of CDC's demonstration efforts have been disseminated in the professional literature and the CDC staff has provided technical assistance to procurement centers interested in increasing organ availability. The CDC results also have applicability in identifying potential donors of many types of organs. Additionally, to underline the need for increased efforts in this area, the President has asked Dr. Koop, Surgeon General of the Public Health Service and a pediatric surgeon, to provide help in stimulating organ donation. To this end, Dr. Koop will sponsor a workshop in June to focus attention on the need and to explore measures to increase the availability of organs for transplantation.

Assessment of Safety and Effectiveness

The Office of Health Technology Assessment (OHTA) within the National Center for Health Services Research has been asked by HCFA to evaluate the safety and effectiveness of heart, pancreas, and liver transplantation. PHS assessment of the heart transplant has been suspended until the Battelle Center National Heart Transplantation Study is completed in April and a report submitted in July. The results of the pancreas assessment should also be available then.

In April, 1982 HCFA asked the PHS to reassess liver transplantation, after the PHS had previously determined the procedure to be experimental in 1980. OHTA, as is its usual practice, has published a notice in the Federal Register about its intent to evaluate these technologies and, at the same time, contacted appropriate Federal agencies, medical specialty societies, and health insurance and manufacturing associations. With material from these sources, information that the NIH Consensus Development Conference on Liver Transplantation generates, and staff review of the literature, OHTA will develop PHS recommendations regarding the safety and effectiveness of liver transplantation for usual circumstances in the practice of medicine for HCFA's use in making coverage decisions. The results of the liver assessment should be available sometime this summer, as well.

Conclusion

The various agencies of the Public Health Service are active in trying to address many of the concerns voiced before this Subcommittee. In describing our activities, I have outlined the role we play in research, drug regulation, public health surveillance and conscience-raising, and technology assessment. I assure you that all of these efforts including those to develop knowledge and explore new treatments will continue in the hope that ultimately research will identify the causes and progression of these diseases, thus preventing the need for organ transplantation.

I would be pleased to answer any questions.

Dr. **Brandt**. With your permission, Mr. Chairman, I would like to now ask Dr. Koop to elaborate on the Conference on Organ Procurement.

Mr. **Gore**. Dr. Koop, we welcome you to the subcommittee. Please proceed.

STATEMENT OF C. EVERETT KOOP, M.D., SURGEON GENERAL, U.S. PUBLIC HEALTH SERVICE

Dr. **Koop**. Thank you, Mr. Chairman.

As a pediatric surgeon for 35 years, I know that there are only two possibilities when a child has true biliary atresia: liver transplantation—not available until recently—or death.

I certainly am moved by the plight of families and their children as they await livers for transplantation. The President and Mrs. Reagan have shown their personal concern for such children and have asked me to help where I could.

However, the problem is broader than just liver transplantation. And it is important not merely to help in the individual case, vital as that may be, but to achieve an increase in the overall supply of organs, for the shortage of organs in future years will be such that pleas will be sounded many times in behalf of adults as well as children as transplantation expertise expands to include other organs.

I am therefore convening a group of experts in Winchester, Virginia, June 7 to 9 this year, to discuss methods of increasing the supply of organs donated for transplantation. The workshop is intended to stimulate members of the private sector so that they will be more effective in focusing their efforts in this area.

The participants will discuss donation of solid organs, of hearts or heart-lung combinations, kidneys, and livers. The state of the art demands that for heart and liver to be considered for transplantation, the prospective donors must be on respirators at the time of death.

In addition, of course, a kidney may be used from a living donor, but most are now taken from cadavers. We hope that any suggested measures will increase the supply of all transplantable organs.

About 40 people will meet at this conference. They will represent a cross section of experts in transplant surgery, brain surgery and brain death, tissue typing, and emergency medicine. Others will include representatives from voluntary associations which promote research and transplantation.

Others will be those who have encouraged relatives to donate organs at the time of deaths in families. Still others will include the family of a child who in death donated organs and the parents of children who needed liver transplants.

Finally, we shall have a group of catalysts, including, for example, an expert on the role of the media, a sociologist, an ethicist, and others.

The aim of the workshop therefore will be to bring together appropriate representatives of public and private sectors to find educational means for the following:

First, to encourage the general public—in particular, relatives of dying people on respirators—to think about the good that might be accomplished through the timely donation of organs.

Second, to encourage the active but compassionate participation of physicians, nurses, and other members of the medical team in the organ procurement process.

Now, sir, the workshop is grounded on some general assumptions. First, it is wise to retain our present voluntary system of organ procurement. We should consider carefully the many disadvantages of trying to require that people contribute organs.

Parenthetically, I might say that one disadvantage is that Americans probably would not readily accept such a duty when, in contrast, they would be quite willing to donate. Indeed, one of the features that must have appealed to State legislators a dozen or so years ago when they accepted the Uniform Anatomical Gift Act was that it contained the word "gift."

Another assumption is related to the first. It is that the government should not try to dictate roles for an effort in which private sector organizations have worked so earnestly. For years, people in the private sector have educated the public on the usefulness of organ donations. Their representatives have approached relatives when deaths occurred to suggest a method whereby a life that was ending would help others.

The conferees will learn about techniques that have been effective in encouraging families and physicians to consider the usefulness of transplantation when a person is on a respirator and is either brain-dead or dying. I trust therefore that I, as well as others, will learn much at this conference.

Having lost a child of my own, I know that parents of dying youngsters seek to find any positive aspect in their loss. One such aspect could be that from the death of one child, four people lived and two received new sight. In the future, this could be more than four as the world of organ transplant evolves.

If we can convince many families to think in these terms, we will have achieved our goal.

Thank you.

[The prepared statement of Dr. Koop follows:]

TESTIMONY ON

SURGEON GENERAL'S WORKSHOP
ON SOLID ORGAN PROCUREMENT FOR TRANSPLANTATION: EDUCATING THE PHYSICIAN AND THE PUBLIC

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

APRIL 27, 1983

C. EVERETT KOOP, M.D.
SURGEON GENERAL
UNITED STATES PUBLIC HEALTH SERVICE

Mr. Chairman and Members of the Subcommittee:

As a pediatric surgeon for thirty-five years, I know that there are only two possibilities when a child has biliary atresia--liver transplantation (not available until recently) or death. I am moved by the plight of families and their children as they await livers for transplantation. The President and Mrs. Reagan have shown their concern for such children and have asked me to help where I could.

However, the problem is broader than just liver transplantation. And it is important not merely to help in individual cases--vital as that may be--but to achieve an increase in the overall supply of organs. For the shortage of organs in future years will be such that pleas will be sounded many times, in behalf of adults as well as children, as transplantation expertise expands to include other organs.

I am therefore convening a group of experts in Winchester, Virginia, June 7 to 9, 1983, to discuss methods for increasing the supply of organs donated for transplantation. The workshop is intended to stimulate members of the private sector so that they will more effectively focus their efforts in this area.

T

The participants will discuss donations of solid organs--of hearts (or heart-lung combinations), kidneys, and livers. The state of the art demands that for those organs to be considered for transplantation, the prospective donors must be on respirators at the time death is declared. (In addition, of course, a kidney may be used from a living donor, but most are taken from cadavers.) We hope that any suggested measures will increase the supply of all transplantable organs.

About forty people will meet. They will represent a cross section of experts in transplant surgery, brain surgery and brain death, tissue typing, and emergency medicine. Others will include representatives of voluntary associations, which promote research and transplantation. Others will be those who have encouraged relatives to donate organs at the time of deaths in families. Still others will include the family of a child who in death donated organs and the parents of children who needed liver transplants. Finally, we shall have a group of catalysts, including, for example, an expert on the role of the media, a sociologist, an ethicist, and others.

The aim of the workshop therefore will be to bring together appropriate representatives of the public and private sector to find educational means for the following:

1. To encourage the general public (in particular, relatives of people on respirators) to think about the good that might be accomplished through the timely donation of organs.

2. To encourage the active but compassionate participation of physicians, nurses, and other medical team members in the organ procurement process.

The workshop is grounded in some general assumptions. First, it is wise to retain our present voluntary system of organ procurement. We should consider carefully the many disadvantages of trying to require that people contribute organs. Parenthetically, I might say that one disadvantage is that Americans probably would not accept such a duty when, in contrast, they would be quite willing to donate. Indeed, one of the features that must have appealed to state legislators a dozen or so years ago when they accepted the Uniform Anatomical Gift Act was that it contained the word gift.

Another assumption is related to the first. It is that the government should not try to dictate roles for an effort in which private-sector organizations have worked so earnestly.

For years, people in the private sector have educated the public on the usefulness of organ donations. Their representatives have approached relatives when deaths occurred to suggest a method whereby a life that was ending would help others.

The conferees therefore will learn about techniques that have been effective in encouraging families and physicians to consider the usefulness of transplantation when a person is on a respirator and is either brain-dead or dying. I trust that I as well as others will learn much.

Having lost a child of my own, I know that parents of dying youngsters seek to find any positive aspect of their loss. One such aspect could be that from the death of one child, three people lived and two received renewed sight. If we can convince many families to think in those terms, we will have achieved our goal.

Mr. **Gore**. Thank you very much. We are going to hold our questions, of course, until the panel has concluded.

Carolyne Davis is Administrator of the Health Care Financing Administration with HHS. Dr. Davis, we are delighted to have you here. Please proceed.

STATEMENT OF CAROLYNE K. DAVIS, PH. D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION; ACCOMPANIED BY DR. DONALD YOUNG

Dr. **Davis**. Thank you very much, Mr. Chairman.

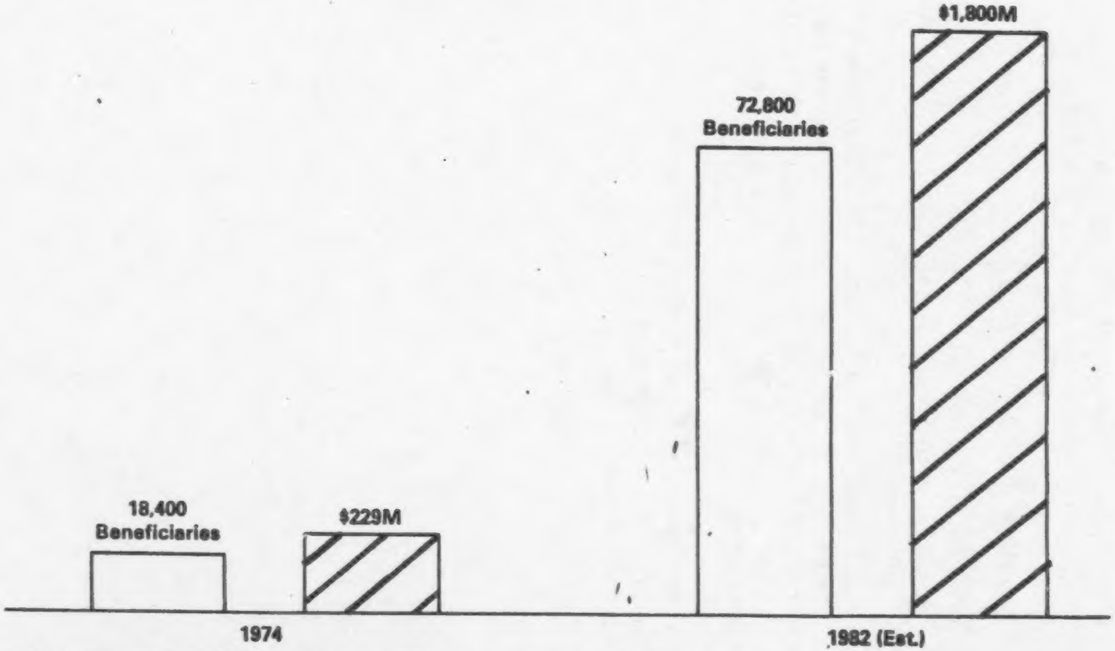
I, too, am pleased to be here. I want to discuss the systems that we have in place for making organs available for transplantation. I will concentrate predominantly on the medicare ESRD program that is administered by HCFA.

As you know, in 1972, legislation provided medicare coverage to virtually all individuals with ESRD. Chart 1 will show you the enormous growth in the program.

[The chart follows:]

CHART 1

ESRD Program Growth



With 0.25% of all medicare enrollees ESRD now accounts for 8.4% of Part B payments and 3.7% of All Medicare payments.

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In 1974, there were 18,400 beneficiaries, and the total cost of the program at that point in time was $229 million.

Today our medicare program protects approximately 93 percent of all of the people who are receiving end-stage renal disease services. The cost in 1982 for 72,800 individuals was about $2 billion. This represents approximately 4 percent of the total program expenditures of medicare and roughly 9 percent of the part B expenditures in medicare.

These expenditures go for one-quarter of 1 percent of our medicare beneficiaries. As you can see, they have grown much faster than they were initially projected when the original law was passed.

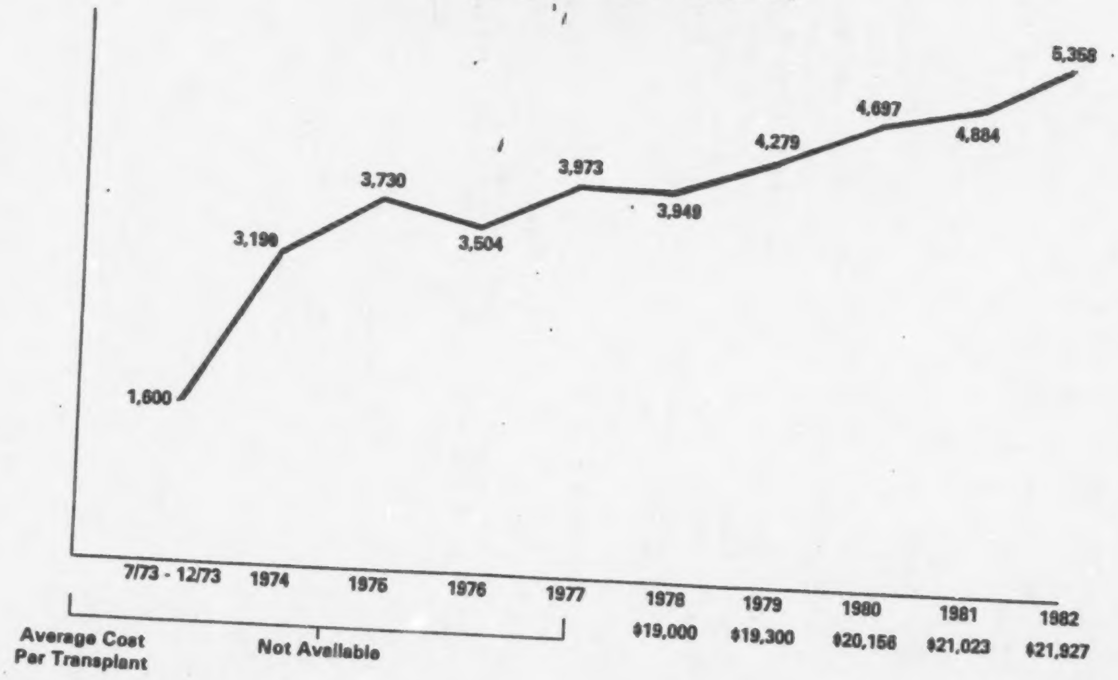
Transplantation, as you know, is one of three types of treatment for ESRD, together with hemodialysis and peritoneal dialysis. In terms of transplantation, there have been approximately 38,650 kidney transplants performed between 1982 and the beginning of the Medicare ESRD program in 1973. We now have roughly 15,700 individuals who are currently still alive and living with a functioning transplanted kidney.

Chart 2 does indicate that in 1982 there was a total of 5,358 kidney transplants. There has been a slight yearly increase, but it is not, I think, as significant an increase as what we would like to see in terms of the overall transplantation efforts of kidneys.

[The chart follows:]

CHART 2

Transplantation
Number of Kidney Transplants
(Medicare and Non-Medicare)



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Cost effectiveness of the kidney transplant program in relationship to the annual dialysis cost is also an important consideration. Recent studies have indicated that the average annual medicare program cost per patient for dialysis, including the physician's fees, is approximately $18,000 a year.

The average medicare program cost for a transplant patient, including all of the services for the first year, is approximately $37,000. Post-transplant annual drug costs are running approximately $2,000.

Now, there are significant differences between the medicare and the medicaid eligibility for all types of transplant recipients. The medicare entitlement is for currently or fully insured individuals who have end-stage renal disease, as well as for the individual spouse or dependent child who contracts the end-stage renal disease.

In contrast, there are no eligibility requirements within the medicaid program that are specific in the area of organ donor transplant. The State has a choice to cover any type of organ transplant service, although generally they do await some guidance as to what is termed experimental. But they have reponsibility of making decisions on individual circumstances. They do require that the individual persons must meet the income and the resource requirements that are standards of the medicaid program in that specific State.

Medicare coverage and reimbursement for the kidney transplant program includes both part A and part B. Part A is the hospital insurance part, that covers the costs of the in-patient hospital services for both the kidney donor and the recipient of the kidney. Part B, of course, covers the surgeon's fee.

We also cover payments to the individuals who perform the cadaver donor excisions, and we pay those at 100 percent of the reasonable costs under part A.

In terms of kidney procurement, the organ procurement agencies, as you know, perform or coordinate the collection of donated organs and their preservation and transportation, and then they maintain a system to locate the prospective recipients for the harvested organs.

I thought you would find chart 3 of interest. It is a chart which indicates the number of the organ procurement programs and their locations. There are 36 independent organ procurement agencies which are designated on the chart by squares. Those independent organ procurement agencies are located in some 22 States and the District of Columbia. These are the ones that participate in our medicare program.

There are approximately 140 hospitals that have their own organ procurement programs, too. These facilities appear as triangles on the map.

I think if you look at chart 4, this clearly indicates that there are 157 certified kidney transplant centers which meet our medicare utilization requirements. The location, as you can see, is somewhat similar to the organ procurement program agencies.

[The charts follow:]

CHART 3

Organ Procurement Programs

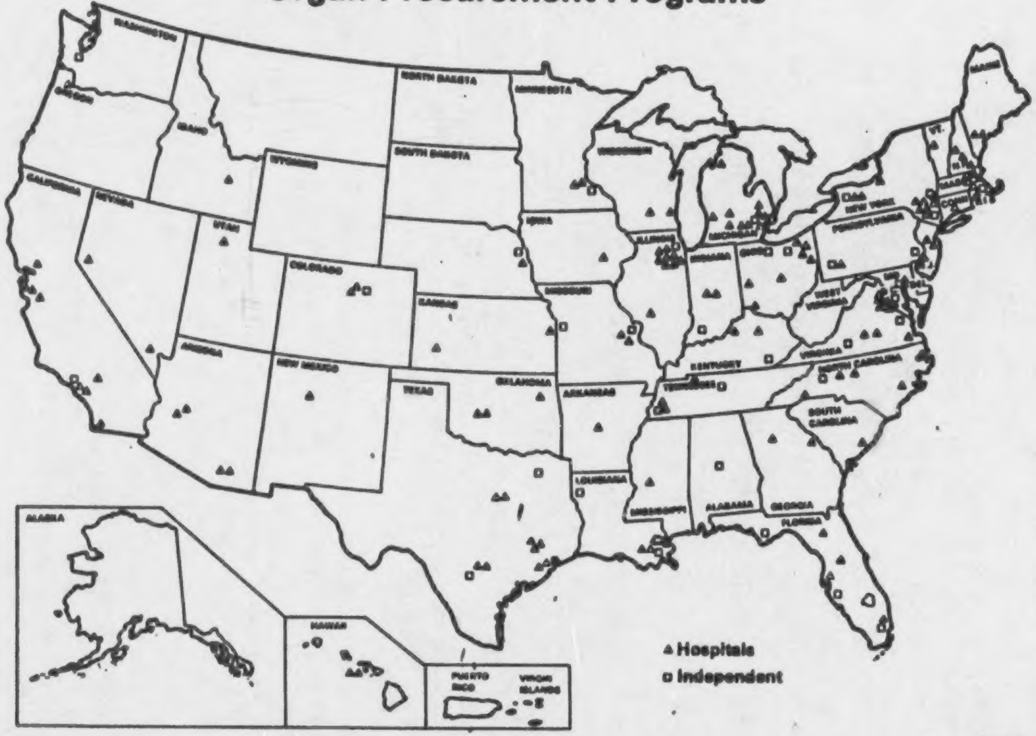
WASHINGTON
OREGON
IDAHO
CALIFORNIA
NEVADA
UTAH
WYOMING
COLORADO
ARIZONA
NEW MEXICO
NORTH DAKOTA
SOUTH DAKOTA
KANSAS
OKLAHOMA
TEXAS
MINNESOTA
IOWA
MISSOURI
ARKANSAS
LOUISIANA
WISCONSIN
ILLINOIS
MICHIGAN
INDIANA
OHIO
KENTUCKY
TENNESSEE
MISSISSIPPI
ALABAMA
GEORGIA
FLORIDA
SOUTH CAROLINA
NORTH CAROLINA
VIRGINIA
WEST VIRGINIA
PENNSYLVANIA
NEW YORK
VT.
MAINE
MASS.
CONN.
ALASKA
HAWAII
PUERTO RICO
VIRGIN ISLANDS
▲ Hospitals
□ Independent

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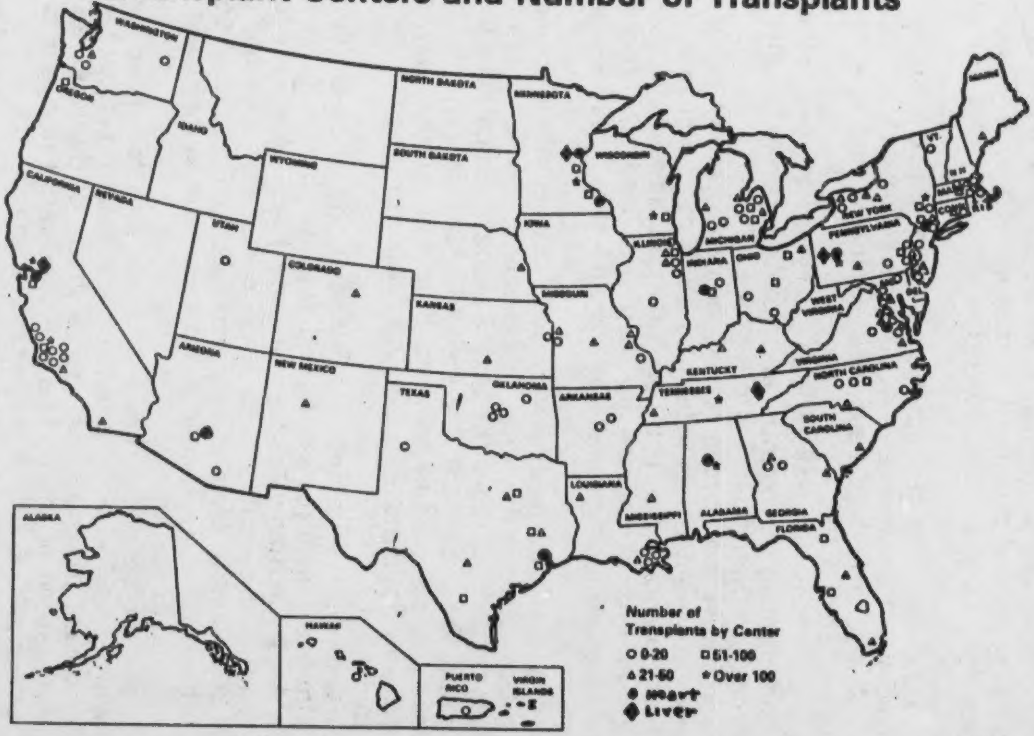
CHART 4

ESRD
Transplant Centers and Number of Transplants


WASHINGTON
OREGON
CALIFORNIA
NEVADA
IDAHO
WYOMING
UTAH
COLORADO
ARIZONA
NEW MEXICO
NORTH DAKOTA
SOUTH DAKOTA
KANSAS
OKLAHOMA
TEXAS
MINNESOTA
IOWA
MISSOURI
ARKANSAS
LOUISIANA
WISCONSIN
ILLINOIS
MICHIGAN
INDIANA
OHIO
KENTUCKY
TENNESSEE
MISSISSIPPI
ALABAMA
GEORGIA
FLORIDA
SOUTH CAROLINA
NORTH CAROLINA
VIRGINIA
WEST VIRGINIA
PENNSYLVANIA
NEW YORK
VT.
N.H.
MAINE
MASS.
CONN.
DEL.
ALASKA
HAWAII
PUERTO RICO
VIRGIN ISLANDS
Number of Transplants by Center
○ 0-20
□ 51-100
△ 21-50
* Over 100
● Heart
◆ Liver

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I would like to point out that of the 157 kidney transplant centers, there are a number of centers in the area that only do under 20 a year, and the number that do under 20 a year is roughly 50 percent. They are the ones that are shown on the chart as white circles.

Likewise, the triangle figures are the transplant centers that transplant between 21 and 50 kidneys a year.

The squares represent those facilities that are transplanting between 51 and 100.

And then the star figures represent centers, of which you will find eight in the country or roughly 5 percent of the total, that are transplanting 100 or more kidneys.

We have one intermediary that does service all of our independent procurement agencies and all of our independent histocompatibility laboratories. The hospitals that have organ procurement programs are reimbursed by their own intermediaries through their kidney acquisition cost center, and that is based upon reasonable cost.

The patients meet a variety of criteria determined by the medical community in order to be candidates for a transplant, and of course that includes the stable medical component in order to withstand the procedure. They should have no secondary types of diagnoses and should be between 10 and 55 years of age, although those criteria do change occasionally according to the medical specifications.

Generally speaking, we find that the same candidates for transplants are also the same candidates for home dialysis programs.

As I mentioned earlier, we did have 72,800 medicare end-stage renal disease patients in 1982, and of those we had approximately 4,900 who did have kidney transplants. Of those, I think it was significant that 3,681 received a cadaveric kidney, and 1,667 received a living donor kidney.

We do know from recent work that has been done by our research staff that a group of transplant patients would cost the medicare program less than a group of dialysis patients after a 4-year period of time when one considers the aggregate costs for the 4-year period for the respective groups.

The survival rates, as you know, have improved dramatically in the last 2 or 3 years. The rehabilitation and the improved quality of life and the work potential have been shown to be the highest for a kidney transplant patient, according to our recent study by Battelle.

We have several studies in the area of transplantation that I would like to mention very briefly. They are covered in detail in my testimony.

We have embarked upon a 5-year plan for research and demonstration in the ESRD area. There are two specific studies I have already mentioned. The Battelle Institute study that we granted in 1981 is looking at the quality of life, the quality of care, and the cost of patients who undergo different types of therapy. It has analyzed 11 renal dialysis centers and facilities and about 900 patients and has concluded that kidney transplant patients and patients who are on home dialysis are more likely to be working and have a lower level of functional impairment.

A second and important study, also, that was begun in 1981 through the Brandeis Health Policy Consortium is looking at methods to increase the public participation in the kidney donation program. This study is addressing methodologies and structures in the area of organ procurement, trying to study the operational efficiency of the independent organ procurement agencies, and to determine what are the most effective ways to obtain and to distribute kidneys.

We hope that we can correlate and analyze the state of the art in the organ procurement area and develop a model for a successful kidney procurement agency and evaluate the differences—and why the differences are there—between the various independent organ procurement agencies.

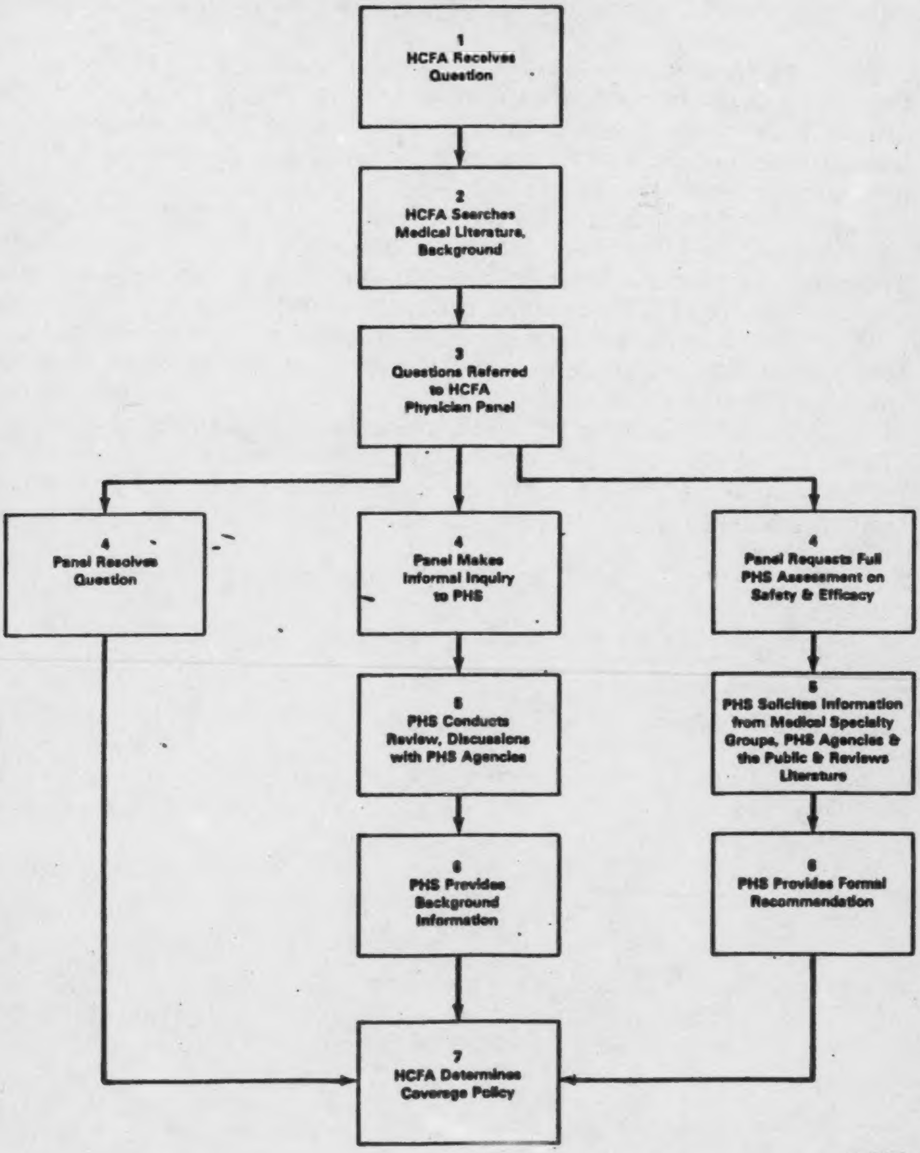
In terms of coverage, the law states that the medicare programs can only pay for those services that are reasonable and necessary. Therefore, medicare does not pay for devices, procedures,or techniques that are still considered investigational.

Chart No. 5 indicates to you how our decisions are made with relationship to medicare coverage. When a coverage issue, such as the possibility of coverage of an organ transplant, is brought to our attention, either by our regional office staff or our fiscal intermediaries, the Office of Coverage Policy conducts a search of the medical literature and looks at any other relevant background material that is available.

[The chart follows:]

CHART 5

How Decisions Are Made Regarding Medicare Coverage


1 HCFA Receives Question
2 HCFA Searches Medical Literature, Background
3 Questions Referred to HCFA Physician Panel
4 Panel Resolves Question
4 Panel Makes Informal Inquiry to PHS
4 Panel Requests Full PHS Assessment on Safety & Efficacy
5 PHS Conducts Review, Discussions with PHS Agencies
5 PHS Solicites Information from Medical Specialty Groups, PHS Agencies & the Public & Reviews Literature
6 PHS Provides Background Information
6 PHS Provides Formal Recommendation
7 HCFA Determines Coverage Policy

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If it appears that the device or the procedure may be investigational, then our HCFA physicians panel reviews the issue. Dr. Donald Young, who is with me today, chairs that panel. Our physicians panel may resolve the question, or they may refer it to the Public Health Service either for an informal inquiry or a request for a full assessment relative to safety and efficacy.

An informal request will usually involve a more intensive review of the medical literature, a discussion with other individuals in the government, and a response to specific questions that may have been raised by our physicians panel.

The full assessment would involve consultation by the Public Health Service with affected medical specialty groups and other professional organizations in ascertaining the consensus within the medical community relative to the safety and efficacy of the service or procedure.

When the Public Health Service has completed their evaluation, they make a formal recommendation to HCFA relative to the safety and efficacy of the device or procedure. HCFA then determines whether the device or the procedure should be covered by medicare.

At the present time, as you know, the medicare program's coverage for organ transplants is limited to kidney and cornea transplants. However, I stressed earlier, and would stress again, that under medicaid, we would match the State's funding for any organ transplant that they choose to cover.

We also are doing a study relative to heart transplants in terms of evaluating all of the aspects of the heart transplantation under medicare. Chart 4 shows that we have 10 heart transplant centers—designated by the black circles—that are doing heart transplantations under the medicare program.

The study is trying to determine the need for heart transplants, survival of the heart transplant recipients, potential availability of donor hearts, costs, rehabilitation, quality of life of heart transplant recipients, and the legal and ethical aspects of heart transplantion.

As part of this study, we are reimbursing a limited number of heart transplants—16 in number. We have already paid for nine transplants that have been performed under this study. The study is scheduled to be completed in April 1984, with the evaluation to be finished 3 months later. Once this particular study is completed, we will be consulting further with the Public Health Service for a decision relative to coverage of heart transplantion under the medicare program.

In terms of liver transplantation, the black diamond-shape figures on Chart 4 indicate the centers that we know are doing liver transplants. They tend to coincide very closely with the other areas where major transplant centers are.

At the end of 1980, the Public Health Service responded to a HCFA request for guidance on liver transplants and stated at that time that they were still investigational. Since that time, cyclosporin A, although it is still experimental, has been used more widely and there seems to be some evidence that it has a favorable effect on liver transplantion.

Therefore, in April 1982, we referred the questions again of safety and efficacy of liver transplants to the Public Health Service for a reassessment. We asked them to consider the questions of coverage in relationship to specific subgroups of the population. We did this specifically because there is some indication that there is a different success rate in liver transplants between children and adults and that the recent breakthroughs may have indeed affected the survival rates more favorably in terms of children.

In terms of pancreatic transplants, we asked the Public Health Service for its recommendations relative to the safety and efficacy of pancreatic transplants, especially those with respect to the end-stage renal disease beneficiary who is a diabetic and who may have undergone a kidney transplant or may wish to undergo a kidney transplant.

In conclusion, Mr. Chairman, as a nurse and as a former health care provider, I have watched with great interest and some degree of excitement the technological advances that have allowed us to prolong life, to prevent and to retard morbidity, and to enhance the quality of life.

But, as the Administrator of HCFA, I have an additional responsibility as the guardian of the trust funds supporting the medicare program to assure that we are reimbursing for the care which is reasonable and necessary as is required by law.

As you know, the trust funds have been recognized as being in some degree of jeopardy in future years. Our actuaries project that the hospital insurance trust fund could be insolvent in 1990, and that we will have to slow the rate of growth of program expenditures by approximately 33 percent or double our payroll taxes in the next decade if we are to assure that that program will continue.

We, of course, must assure ourselves that we are providing the ability to pay for the health care for those aged and disabled who are entitled to the medicare program. Therefore, the health incentives reform proposals we submitted in our 1984 budget are another step toward slowing the growth. We also need to carefully assess all new technologies and weigh their benefits and costs carefully.

I do not pretend that there are any easy answers to the critical problems, but I think I would be remiss if I did not raise these particular issues.

I do feel strongly that the trust moneys should be spent only on procedures and care that is generally accepted by the medical community as safe and efficacious, and, indeed, the law requires that medicare pay only for the services which are reasonable and necessary.

I do think that is particularly important in these days of escalating health care costs. We are carefully considering, in close consultation with our medical experts in the Public Health Service, all decisions on safety and efficacy of all transplant procedures before we permit further coverage under the medicare program.

I look forward to working with both the Public Health Service and Congress as we continue to look at these important issues, and I thank you for raising the issues.

[The prepared statement of Dr. Davis follows:]

STATEMENT OF

CAROLYNE K. DAVIS, PH. D.

ADMINISTRATOR

HEALTH CARE FINANCING ADMINISTRATION

INTRODUCTION

MR. CHAIRMAN, I AM CAROLYNE K. DAVIS, THE ADMINISTRATOR OF THE HEALTH CARE FINANCING ADMINISTRATION (HCFA).

I AM PLEASED TO BE HERE TO DISCUSS THE SYSTEMS WHICH ARE IN PLACE FOR MAKING ORGANS AVAILABLE FOR TRANSPLANTATION. I WILL CONCENTRATE MY COMMENTS TODAY ON THE MEDICARE END-STAGE RENAL DISEASE (ESRD) PROGRAM, WHICH IS MANDATED UNDER PUBLIC LAW 92-603 (THE SOCIAL SECURITY AMENDMENTS OF 1972) AND PUBLIC LAW 95-292 (WHICH WAS ENACTED IN 1978) AND ADMINISTERED BY HCFA.

ESRD RESPONSIBILITIES

IN 1972, CONGRESS GAVE THE FEDERAL GOVERNMENT A UNIQUE ROLE BY PROVIDING MEDICARE PROTECTION TO VIRTUALLY ALL PERSONS WITH ESRD. CURRENTLY, MEDICARE PROTECTS APPROXIMATELY 93 PERCENT OF PEOPLE RECEIVING ANY ESRD SERVICES.

MEDICARE COSTS FOR ESRD PATIENTS WERE ABOUT $2 BILLION IN 1982. THIS WAS ABOUT FOUR PERCENT OF TOTAL PROGRAM EXPENDITURES AND REPRESENTS ABOUT NINE PERCENT OF PART B EXPENDITURES. THESE EXPENDITURES WERE FOR ONE QUARTER OF ONE PERCENT OF MEDICARE BENEFICIARIES, AND THEY HAVE GROWN MUCH FASTER THAN WERE ORIGINALLY PROJECTED WHEN THE LAW WAS PASSED.

IN JULY 1973, AT THE BEGINNING OF THE MEDICARE ESRD PROGRAM, THERE WERE APPROXIMATELY 15,000 ESRD PATIENTS, OF WHOM 1,500 RECEIVED TRANSPLANTS. IN 1978, PUBLIC LAW 95-292 WAS ENACTED TO ENCOURAGE EFFICIENCY AND ECONOMY IN THE ESRD PROGRAM. IN PARTICULAR, THE LEGISLATION ENCOURAGED SELF-DIALYSIS AND TRANSPLANTATION TO REDUCE LONG-TERM PROGRAM COSTS.

TO UNDERSTAND THE TREATMENT OF ESRD, I WOULD LIKE TO BRIEFLY DESCRIBE THE NATURE OF ESRD. AS YOU KNOW, THE FUNCTION OF HUMAN KIDNEYS IS TO COLLECT AND DISPOSE OF BODY WASTES FORMED IN THE BLOOD DURING METABOLISM. ESRD IS A PERMANENT AND IRREVERSIBLE BREAKDOWN OF THE CAPACITY OF THE KIDNEYS TO CARRY OUT THIS DISPOSAL FUNCTION. ESRD REQUIRES ARTIFICIAL REMOVAL OF THESE WASTES THROUGH DIALYSIS OR REPLACEMENT OF THE KIDNEY THROUGH TRANSPLANTATION. FAILURE TO PROVIDE TREATMENT RESULTS IN DEATH.

THERE ARE TWO TYPES OF DIALYSIS TREATMENT: HEMODIALYSIS AND PERITONEAL DIALYSIS. AT THE END OF 1982, 82 PERCENT OF ESRD PATIENTS WERE TREATED IN A DIALYSIS FACILITY AND 18 PERCENT OF ESRD PATIENTS WERE ON HOME DIALYSIS.

HEMODIALYSIS, THE MORE WIDELY USED DIALYSIS MODALITY, FILTERS BLOOD THROUGH AN ARTIFICIAL KIDNEY MACHINE TO REMOVE WASTES BEFORE THE BLOOD IS RETURNED TO THE BODY. HEMODIALYSIS MAY BE PERFORMED IN A DIALYSIS FACILITY, WHICH MAY BE A

HOSPITAL OR A FREESTANDING FACILITY, OR IN THE HOME AT A LESSER COST. AT THE END OF 1982, 83 PERCENT OF HEMODIALYSIS ESRD PATIENTS WERE TREATED IN A DIALYSIS FACILITY AND 17 PERCENT OF ESRD PATIENTS WERE ON HOME DIALYSIS.

IN PERITONEAL DIALYSIS, THE FILTERING TAKES PLACE WITHIN THE PATIENT'S ABDOMINAL CAVITY WITHOUT THE BLOOD LEAVING THE BODY. PERITONEAL DIALYSIS MAY BE PERFORMED IN A DIALYSIS FACILITY, WHICH MAY BE A HOSPITAL OR A FREESTANDING FACILITY, IN THE HOME, OR ON AN AMBULATORY BASIS. AT THE END OF 1982 MORE THAN 56 PERCENT OF HOME DIALYSIS PATIENTS WERE TREATED BY CONTINUOUS AMBULATORY PERITONEAL DIALYSIS.

IN 1981, THE CONGRESS DIRECTED HCFA TO ENCOURAGE HOME DIALYSIS THROUGH INCENTIVES IN A REVISED RATE STRUCTURE. IN DOING THIS, THE CONGRESS RECOGNIZED THAT HOME DIALYSIS OFFERS GREAT POTENTIAL FOR THE IMPROVEMENT OF THE QUALITY OF LIFE FOR THOSE ESRD PATIENTS WHOSE DOCTORS BELIEVE THEY ARE ELIGIBLE FOR THIS MODALITY.

TRANSPLANTATION IS THE OTHER MAJOR TREATMENT FOR ESRD AND IS MORE DIRECTLY THE SUBJECT OF THE HEARING TODAY. TRANSPLANTATION IS THE SURGICAL PROCEDURE WHICH INVOLVES IMPLANTING KIDNEYS FROM LIVING DONORS OR CADAVERS INTO ESRD PATIENTS. IN 1982, APPROXIMATELY 31 PERCENT OF THE 5,358 TRANSPLANTS PERFORMED INVOLVED LIVING RELATED DONORS. TRANSPLANTS FROM LIVING RELATED DONORS ARE PREFERRED BY TRANSPLANT

SURGEONS AND HAVE YIELDED A LOWER REJECTION RATE. THIS COULD CHANGE WITH IMPROVEMENTS IN IMMUNOSUPPRESSANT DRUGS.

BETWEEN 1973 AND 1982, THERE HAVE BEEN APPROXIMATELY 38,650 TRANSPLANTS PERFORMED. AS OF THE END OF 1982, THERE WERE APPROXIMATELY 16,000 PEOPLE WITH FUNCTIONING GRAFTS. AS OF DECEMBER 31, 1982, THERE WERE 65,763 DIALYSIS PATIENTS AND ABOUT 6,700 OF THESE PATIENTS WERE ON A TRANSPLANT WAITING LIST. IT IS DIFFICULT TO ASSESS THE ACTUAL PERCENTAGE OF THIS POPULATION WHO WOULD BE ELIGIBLE FOR TRANSPLANTATION AT ANY GIVEN POINT IN TIME DUE TO A VARIETY OF FACTORS SUCH AS WILLINGNESS OF PATIENTS, CO-MORBID CONDITIONS, AND LACK OF UNIFORM STANDARD MEDICAL PATIENT SELECTION PROTOCOLS. THE NUMBER OF TRANSPLANTS PERFORMED OVER THE LAST FEW YEARS HAS NOT INCREASED PROPORTIONATELY WITH INCREASES IN THE OVERALL ESRD POPULATION. ONE SHOULD REALIZE THAT THE ESRD POPULATION IS CHARACTERIZED BY OLDER AND SICKER PATIENTS EACH YEAR.

THE COST-EFFECTIVENESS OF TRANSPLANTATION CAN BE CONSIDERED IN RELATION TO ANNUAL DIALYSIS COSTS. THE AVERAGE ANNUAL MEDICARE PROGRAM COSTS FOR DIALYSIS INCLUDING PHYSICIANS' FEES IS $18,000. THE AVERAGE MEDICARE PROGRAM COSTS PER TRANSPLANT PATIENT INCLUDING ALL SERVICES IS APPROXIMATELY $37,000 FOR THE FIRST YEAR OF TRANSPLANT. IN ADDITION, ACCORDING TO A MAJOR ESRD STUDY CURRENTLY UNDERWAY, POST-TRANSPLANT ANNUAL DRUG COSTS ARE APPROXIMATELY $2,000.

MEDICARE/MEDICAID ELIGIBILITY FOR TRANSPLANT RECIPIENTS

THE SOCIAL SECURITY ACT PROVIDES MEDICARE ENTITLEMENT FOR CURRENTLY OR FULLY INSURED INDIVIDUALS WITH END-STAGE RENAL DISEASE WHO REQUIRE REGULAR KIDNEY DIALYSIS OR RECEIVE A KIDNEY TRANSPLANT. THIS COVERAGE ALSO APPLIES TO THE INDIVIDUAL'S SPOUSE OR DEPENDENT CHILD IF ONE OF THEM CONTRACTS ESRD AND INITIATES DIALYSIS OR RECEIVES A TRANSPLANT.

THE FIRST DAY OF COVERAGE FOR MEDICARE VARIES DEPENDING ON THE MODE OF TREATMENT. IN GENERAL, AN INDIVIDUAL ON DIALYSIS RECEIVES BENEFITS THREE MONTHS AFTER THE START OF DIALYSIS, OR IF AN INDIVIDUAL ELECTS HOME DIALYSIS, COVERAGE BEGINS ONE MONTH AFTER A COURSE OF HOME DIALYSIS COMMENCES. AN INDIVIDUAL WHO RECEIVES A KIDNEY TRANSPLANT BEGINS COVERAGE WITH THE MONTH OF THE TRANSPLANT OR 2 MONTHS EARLIER IF HE OR SHE IS HOSPITALIZED IN PREPARATION FOR THE TRANSPLANT.

COVERAGE ENDS 36 MONTHS AFTER THE MONTH OF TRANSPLANT UNLESS THE TRANSPLANT FAILS AND THE INDIVIDUAL BEGINS A COURSE OF DIALYSIS OR RECEIVES ANOTHER TRANSPLANT.

THERE ARE NO ELIGIBILITY REQUIREMENTS IN THE MEDICAID PROGRAM THAT ARE SPECIFIC TO PERSONS WHO REQUIRE ORGAN TRANSPLANTS. PERSONS WHO REQUIRE ORGAN TRANSPLANTS MUST MEET THE SAME CATEGORICAL AND INCOME AND RESOURCE STANDARDS THAT ALL

OTHER PERSONS MUST MEET IN ORDER TO BECOME ELIGIBLE FOR MEDICAID. IF THESE REQUIREMENTS ARE MET, THE INDIVIDUAL IS ELIGIBLE FOR ANY OF THE MEDICAID PROGRAM SERVICES OFFERED BY HIS/HER PARTICULAR STATE. THE AVAILABILITY OF ORGAN TRANSPLANTS TO A MEDICAID-ELIGIBLE THEN DEPENDS ON WHETHER A STATE HAS CHOSEN TO COVER SUCH SERVICES UNDER ITS MEDICAID PLAN.

MEDICARE COVERAGE AND REIMBURSEMENT FOR KIDNEY TRANSPLANTATION

BOTH PARTS A AND B (HOSPITAL INSURANCE AND SUPPLEMENTAL MEDICAL INSURANCE) OF MEDICARE HELP PAY FOR KIDNEY TRANSPLANT SURGERY. PART A HOSPITAL INSURANCE WILL COVER THE COSTS OF INPATIENT HOSPITAL SERVICES FOR BOTH THE KIDNEY RECIPIENT AND THE DONOR. THESE SERVICES MAY INCLUDE A PRE-EVALUATION, THE KIDNEY PROCUREMENT, AND THE ACTUAL TRANSPLANT OPERATION. PART B MEDICAL INSURANCE WILL PAY FOR A SURGEON'S RENAL TRANSPLANTATION SERVICES ON A COMPREHENSIVE PAYMENT BASIS FOR SERVICES RENDERED DURING A 60-DAY PERIOD. THE PAYMENT CAN VARY DEPENDING ON WHETHER THE RENAL SURGEON PERFORMED OTHER SURGICAL PROCEDURES AT THE TIME OF THE TRANSPLANTATION OR WHETHER HE/SHE PROVIDED SUPERVISION OF THE IMMUNOSUPPRESSANT THERAPY OVER A PERIOD OF 60 DAYS FOLLOWING SURGERY. THIS PAYMENT IS A VARIATION OF THE REASONABLE CHARGE METHOD USED BY THE MEDICARE PROGRAM TO PAY FOR ALL PHYSICIANS' SERVICES. THE MAXIMUM PROGRAM AMOUNTS CURRENTLY ALLOWED BY MEDICARE CARRIERS FOR RENAL TRANSPLANTATION BY A SURGEON, INCLUDING IMMUNOSUPPRESSANT THERAPY FOR 60 DAYS, RANGE FROM $1,734 TO $2,875.

PAYMENT TO SURGEONS WHO PERFORM CADAVERIC DONOR EXCISIONS IS MADE AT 100 PERCENT OF THE REASONABLE COST UNDER PART A. A RECENT INTERMEDIARY SURVEY INDICATED THAT A MEDIAN COST OF APPROXIMATELY $800 IS PAID BY INDEPENDENT ORGAN PROCUREMENT AGENCIES FOR A SURGEON'S REMOVAL OF CADAVERIC KIDNEYS. ALL PHYSICIANS' SERVICES RENDERED IN CONNECTION WITH REMOVAL OF THE LIVING DONOR'S KIDNEY ARE REIMBURSED USING MEDICARE REASONABLE CHARGES. AVERAGE PAYMENTS ARE APPROXIMATELY $1,100 FOR THIS SERVICE.

KIDNEY PROCUREMENT

ORGAN PROCUREMENT IS PERFORMED BY ORGAN PROCUREMENT AGENCIES (OPAS). THESE AGENCIES PERFORM OR COORDINATE HARVESTING OF DONATED ORGANS, PRESERVATION OF DONATED KIDNEYS, TRANSPORTATION OF DONATED KIDNEYS, AND MAINTENANCE OF A SYSTEM TO LOCATE PROSPECTIVE RECIPIENTS FOR HARVESTED ORGANS.

THERE ARE 36 INDEPENDENT OPAS LOCATED IN 22 STATES AND THE DISTRICT OF COLUMBIA WHICH ARE CERTIFIED TO PARTICIPATE IN MEDICARE. IN ADDITION, APPROXIMATELY 140 HOSPITALS HAVE THEIR OWN ORGAN PROCUREMENT PROGRAMS.

THE INDEPENDENT OPAS USUALLY COORDINATE A NETWORK OF PARTICIPATING

HOSPITALS THAT HAVE AGREED TO IDENTIFY POTENTIAL KIDNEY DONORS. OPA PERSONNEL GO TO A HOSPITAL AFTER REMOVAL OF KIDNEY TISSUE TO PRESERVE THE TISSUE IN THE APPROPRIATE APPARATUS. AN OPA TRANSPLANT COORDINATOR IS RESPONSIBLE FOR TRANSPORTING DONATED KIDNEYS FROM THE DONOR SITE TO THE TRANSPLANT HOSPITAL FOR TRANSPLANTATION. THERE ARE 157 CERTIFIED TRANSPLANT CENTERS WHICH MEET MEDICARE UTILIZATION REQUIREMENTS.

COMPUTER MATCHING SYSTEMS HAVE BEEN DEVELOPED TO PERMIT EFFECTIVE ORGAN SHARING BETWEEN GEOGRAPHICALLY DISTINCT TRANSPLANT CENTERS. OPAS ARE RESPONSIBLE FOR LOCATING THE BEST RECIPIENT MATCH FOR THE DONATED KIDNEY.

ONE INTERMEDIARY, AETNA LIFE AND CASUALTY OF HARTFORD, CONNECTICUT, SERVICES ALL INDEPENDENT OPAS AND ALL INDEPENDENT HISTOCOMPATIBILITY (TISSUE TYPING) LABORATORIES. HOSPITALS HAVING THEIR OWN OPAS ARE REIMBURSED BY THEIR INTERMEDIARIES THROUGH THEIR KIDNEY ACQUISITION COST CENTERS. MEDICARE REIMBURSEMENT FOR PROCUREMENT SERVICES PROVIDED BY THESE ENTITIES IS BASED ON REASONABLE COST.

TRANSPLANTATION PATIENT BACKGROUND

TRANSPLANTATION IS NOT A TREATMENT THAT IS SUITABLE FOR ALL ESRD PATIENTS. PATIENTS WHO ARE GOOD TRANSPLANT CANDIDATES MUST MEET A VARIETY OF CRITERIA DETERMINED BY THE MEDICAL

COMMUNITY. USUALLY, TRANSPLANT CANDIDATES MUST BE SUFFICIENTLY STABLE MEDICALLY TO TOLERATE THE PROCEDURE, AND HAVE NO SECONDARY DIAGNOSIS, AND BE BETWEEN 10 AND 55 YEARS OF AGE. IT IS IMPORTANT TO NOTE THAT THE POOL OF PATIENTS FOR TRANSPLANT ARE USUALLY THE SAME PEOPLE WHO ARE CANDIDATES FOR HOME DIALYSIS.

AS I NOTED EARLIER, THERE WERE APPROXIMATELY 15,000 PATIENTS AT THE BEGINNING OF THE MEDICARE ESRD PROGRAM OF WHOM 1,500 HAD BEEN TRANSPLANTED. IN 1982, THERE WERE MORE THAN 70,000 ESRD PATIENTS AND 5,358 TRANSPLANTS PERFORMED. OF THE 5,358 TRANSPLANTS PERFORMED LAST YEAR, 1,667 WERE FROM LIVING RELATED DONORS AND 3,681 USED CADAVERIC KIDNEYS.

POST TRANSPLANT SERVICES FOR SUCCESSFUL PATIENTS INCLUDE PERIODIC OUTPATIENT EXAMINATIONS TO MONITOR FOR REJECTION, TO PRESCRIBE MEDICATIONS, AND TO MONITOR FOR RECURRENCE OF KIDNEY DISEASE.

A GROUP OF TRANSPLANT PATIENTS WILL COST THE MEDICARE PROGRAM LESS THAN A GROUP OF DIALYSIS PATIENTS AFTER FOUR YEARS WHEN CONSIDERING AGGREGATE COSTS ACROSS THE FOUR-YEAR PERIOD FOR THE RESPECTIVE GROUPS.

SURVIVAL OF TRANSPLANT PATIENTS

SURVIVAL RATES OF TRANSPLANT PATIENTS HAVE IMPROVED DRAMATICALLY IN THE LAST TWO TO THREE YEARS. RECENT EXPERIENCES AT THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, AND AT THE UNIVERSITY OF MINNESOTA SHOW A LIVING RELATED DONOR GRAFT SURVIVAL RATE OF 95 PERCENT IN ONE YEAR. THIS IS DUE TO A NEW TECHNIQUE CALLED DONOR SPECIFIC TRANSFUSION WHICH ENABLES PHYSICIANS TO PERFORM A SUCCESSFUL KIDNEY TRANSPLANT FROM A DONOR WITH PRONOUNCED GENETIC DIFFERENCES FROM THE RECIPIENT. IN ADDITION, THE USE OF THE EXPERIMENTAL DRUG CYCLOSPORIN A HAS REDUCED KIDNEY REJECTION BY HALF AND HAS REDUCED INFECTIONS IN TRANSPLANT SURGERY. (ACCORDING TO TRANSPLANT SURGEONS AT THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, AND THE UNIVERSITY OF MINNESOTA, THEIR RECENT TRANSPLANT EXPERIENCES SHOW THAT THEIR RESPECTIVE HOSPITAL COSTS HAVE BEEN REDUCED BY 40 PERCENT THROUGH DECREASING THE LENGTH OF STAY AND THE NEED FOR READMISSION BY USING CYCLOSPORIN A.

REHABILITATION, IMPROVED QUALITY OF LIFE, AND WORK POTENTIAL APPEAR TO BE THE HIGHEST FOR TRANSPLANTED PATIENTS. INDIVIDUAL STATISTICS OF MANY FACILITIES WHICH PERFORM TRANSPLANTATION INDICATE THAT 40 PERCENT OR MORE OF THEIR SUCCESSFUL TRANSPLANT PATIENTS RETURN TO AN EQUAL OR HIGHER LEVEL OF WORK AND QUALITY OF LIFE THAN WHAT THEY HAD ENJOYED PRIOR TO THE ONSET OF ESRD. FOR THESE REASONS, AS WELL AS ANTICIPATED

PROGRAM SAVINGS, I HAVE BEEN ANXIOUS TO WORK TO INCREASE TRANSPLANTATION DURING MY TENURE AS ADMINISTRATOR, AND I AM PARTICULARLY PLEASED THAT NEW TECHNOLOGY WILL AID US IN WORKING TOWARD THE GOAL OF INCREASING TRANSPLANTS.

RESEARCH AND DEMONSTRATION PROJECTS IN TRANSPLANTATION

RESEARCH AND DEMONSTRATION IS AN IMPORTANT AGENCY ACTIVITY ESPECIALLY IN ESRD AND TRANSPLANTATION BECAUSE OF THE ESCALATING COSTS ASSOCIATED WITH THE TYPE OF CARE NEEDED BY THE ESRD PATIENT. HCFA CURRENTLY HAS A FIVE-YEAR PLAN FOR RESEARCH AND DEMONSTRATION PROJECTS IN THE ESRD AREA, INCLUDING TRANSPLANTATION. SPECIFICALLY, WE HAVE TWO MAJOR STUDIES GOING ON WHICH I WOULD LIKE TO DESCRIBE FOR THE SUBCOMMITTEE.

THROUGH A GRANT TO BATTELLE MEMORIAL INSTITUTE IN 1981, HCFA IS LOOKING AT "THE IMPACT OF ALTERNATIVE TYPES OF THERAPY ON PATIENTS WITH END-STAGE RENAL DISEASE." AMONG OTHER THINGS, THE STUDY FOCUSES ON SEVERAL VARIABLES, INCLUDING AN EXAMINATION OF THE QUALITY OF LIFE, THE QUALITY OF CARE, AND THE COST OF CARE TO PATIENTS UNDERGOING DIFFERENT TYPES OF THERAPY FOR TREATMENT OF ESRD. FOUR TREATMENT MODALITIES ARE INCLUDED IN THE STUDY--FACILITY DIALYSIS, HOME DIALYSIS, CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD), AND RENAL TRANSPLANTATION.

THIS STUDY, WHICH IS BASED ON AN ANALYSIS OF 859 ESRD PATIENTS

FROM 11 RENAL DIALYSIS CENTERS AND FACILITIES, HAS ALREADY PROVIDED US WITH SOME INTERIM FINDINGS WHICH ARE RELEVANT TO OUR DISCUSSION OF TRANSPLANTATION TODAY. IN PARTICULAR, SIX MAJOR PAPERS HAVE BEEN WRITTEN TO DATE AND MORE ARE EXPECTED AS THE STUDY ENTERS ITS LAST YEAR.

A FEW OF THE HIGHLIGHTS FROM SOME OF THE PAPERS ARE AS FOLLOWS:

- PATIENTS WITH KIDNEY TRANSPLANTATION AND PATIENTS ON HOME HEMODIALYSIS ARE MORE LIKELY TO BE WORKING AND HAVE A LOWER LEVEL OF FUNCTIONAL IMPAIRMENT.

- RESULTS SUGGEST THAT AFTER PATIENT CASE-MIX HAS BEEN CONTROLLED TREATMENT MODALITIES MAY BE RANKED ACCORDING TO THE QUALITY OF LIFE ASSOCIATED WITH THEM. KIDNEY TRANSPLANT PATIENTS CONSISTENTLY REPORT A HIGHER QUALITY OF LIFE THAN PATIENTS ON OTHER TREATMENT MODALITIES ALTHOUGH IN MANY RESPECTS HOME HEMODIALYSIS PATIENTS ARE SIMILAR.

- ON ALL QUALITY OF LIFE INDICATORS, KIDNEY TRANSPLANT PATIENTS WERE FOUND TO DO BETTER THAN EITHER CAPD OR IN-CENTER HEMODIALYSIS PATIENTS.

- COMPARISONS BETWEEN ESRD TRANSPLANT PATIENTS AND THE GENERAL POPULATION ACROSS THE SUBJECTIVE INDICATORS

OF THE QUALITY OF LIFE DID NOT REVEAL ANY SIGNIFICANT DIFFERENCES.

- KIDNEY TRANSPLANT PATIENTS EXPERIENCE THE LEAST FUNCTIONAL IMPAIRMENT, FOLLOWED BY HOME HEMODIALYSIS PATIENTS, PATIENTS WHO HAD A FAILED KIDNEY TRANSPLANT, IN-CENTER HEMODIALYSIS PATIENTS AND LASTLY CAPD PATIENTS.

- WORK DISABILITY AMONG PATIENTS VARIED BY TREATMENT MODALITY WITH TRANSPLANT PATIENTS MOST LIKELY TO BE WORKING.

- KIDNEY TRANSPLANT PATIENTS, BOTH THOSE WITH FAILED AND THOSE WITH FUNCTIONING GRAFTS, USED MORE REHABILITATION SERVICES THAN THE OTHER PATIENT GROUPS.

- WHEN THE DATA ARE NOT ADJUSTED FOR CASE-MIX DIFFERENCES (AGE, SEX, RACE, EDUCATION, WEALTH, AND HEALTH), SIGNIFICANT DIFFERENCES IN LABOR FORCE PARTICIPATION ARE OBSERVED IN ALL FOUR TREATMENT MODALITIES.

  - IN PARTICULAR, KIDNEY TRANSPLANT PATIENTS ARE MORE LIKELY TO BE WORKING FOLLOWED BY PATIENTS ON HOME HEMODIALYSIS, IN-CENTER HEMODIALYSIS, AND CAPD.

- However, once patient case-mix differences are controlled, several of the differences are reduced. Only kidney transplant patients have a clearly greater participation in the work force after case-mix differences are controlled.

In the fall of 1981, the University Health Policy Consortium began a multi-year study into "Methods for Increasing Public Participation in Kidney Donation Programs." The study addresses the methodologies and structure of organ procurement. The first phase of this HCFA-sponsored grant was to study the operational efficiency of the Independent Organ Procurement Agencies and to measure their effectiveness in obtaining and distributing kidneys.

One of the goals of this study is to correlate and analyze the state of the art in organ procurement in order to develop a model of a successful kidney procurement agency. A second goal is to describe and evaluate differences among Independent Organ Procurement Agencies.

While there are some areas of agreement among Independent Organ Procurement Agencies, there are certainly many areas of disagreement and controversy. For example, under the study we learned that public education is the most controversial aspect of organ procurement. The study has indicated that some Independent Organ Procurement Agencies believe that

PUBLIC EDUCATION IS INEFFECTIVE AND SHOULD NOT BE PART OF ORGAN PROCUREMENT EFFORTS. OTHER INDEPENDENT ORGAN PROCUREMENT AGENCIES CONSIDER PUBLIC EDUCATION TO BE SUCCESSFUL AND THINK THAT THE PUBLIC ATTITUDE INFLUENCES THE WILLINGNESS OF MEDICAL PROFESSIONALS TO ASSIST IN PROCUREMENT EFFORTS.

THROUGH OUR GRANT SOLICITATION PROCESS, WE ARE CURRENTLY LOOKING FOR PROPOSED APPROACHES TO ANALYZE DIFFERENCES IN OUTCOMES AND RELATED FACTORS IN KIDNEY TRANSPLANTS AND DEVELOPMENT AND TESTING OF SYSTEMS THAT INCLUDE INCENTIVES TO PROMOTE AVAILABILITY OF KIDNEYS. IN ADDITION TO THESE TOPICS, WE PUBLISHED OTHER TOPICS FOR STUDY IN ESRD IN THE APRIL 6TH EDITION OF THE FEDERAL REGISTER. RENAL STUDIES WILL BE REVIEWED AS PART OF OUR NEXT GRANTS APPLICATION CYCLE. WE HOPE THAT FUTURE RESEARCH ON ESRD ISSUES WILL PROVIDE THE NEEDED DATA TO REVISE AND RESHAPE OUR POLICIES AFFECTING THIS SEVERELY ILL POPULATION.

COVERAGE DECISIONS AND ACTIVITIES

THE LAW STATES THAT MEDICARE SHOULD PAY ONLY FOR THOSE SERVICES WHICH ARE REASONABLE AND NECESSARY. THEREFORE, MEDICARE DOES NOT PAY FOR DEVICES, PROCEDURES, OR TECHNIQUES THAT ARE CONSIDERED TO BE INVESTIGATIONAL. WHEN A COVERAGE ISSUE SUCH AS AN ORGAN TRANSPLANT IS BROUGHT TO HCFA'S ATTENTION--BY, FOR EXAMPLE, ONE OF OUR FISCAL CONTRACTORS OR A REGIONAL OFFICE - THE OFFICE OF COVERAGE POLICY CONDUCTS

A SEARCH OF THE MEDICAL LITERATURE AND ALSO REVIEWS ANY OTHER BACKGROUND MATERIAL THAT HAS BEEN SUBMITTED REGARDING THE ISSUE. IF IT APPEARS FROM THESE REVIEWS THAT THE DEVICE OR PROCEDURE MAY BE IN AN INVESTIGATIONAL STATE OF DEVELOPMENT, THE ISSUE IS REFERRED TO THE HCFA PHYSICIANS PANEL FOR REVIEW. THAT PANEL EITHER RESOLVES THE QUESTION OR REFERS IT TO THE PUBLIC HEALTH SERVICE (PHS) ON EITHER AN INFORMAL INQUIRY BASIS OR WITH A REQUEST FOR A FULL ASSESSMENT AS TO SAFETY AND EFFICACY. INFORMAL REQUESTS USUALLY INVOLVE A MORE INTENSIVE REVIEW OF THE MEDICAL LITERATURE, DISCUSSIONS WITH OTHER GOVERNMENT COMPONENTS, AND CLARIFICATION OF, AND RESPONSE TO, SPECIFIC QUESTIONS RAISED BY THE PANEL.

A FULL ASSESSMENT AS TO SAFETY AND EFFICACY INVOLVES THE CONSULTATION WITH AFFECTED MEDICAL SPECIALTY GROUPS AND OTHER PROFESSIONAL ORGANIZATIONS AND THE GATHERING OF INFORMATION AS TO THE CONSENSUS WITHIN THE MEDICAL COMMUNITY REGARDING THE SAFETY AND EFFICACY OF THE SERVICE OR PROCEDURE. WHEN PHS HAS COMPLETED THE INFORMATION-GATHERING AND EVALUATION PROCESS, IT MAKES A FORMAL RECOMMENDATION TO HCFA WITH RESPECT TO THE SAFETY AND EFFICACY OF THE DEVICE OR PROCEDURE, AND HCFA THEN DECIDES WHETHER THE DEVICE OR PROCEDURE SHOULD BE COVERED BY MEDICARE.

AT PRESENT, THE MEDICARE PROGRAM'S COVERAGE OF ORGAN TRANSPLANTS IS LIMITED TO KIDNEY AND CORNEA TRANSPLANTS. UNDER THE

MEDICAID PROGRAM, WE PRESENTLY MATCH THE STATES' FUNDS FOR ANY ORGAN TRANSPLANT THEY CHOOSE TO COVER.

THE QUESTION OF MEDICARE COVERAGE HAS ARISEN WITH RESPECT TO COVERAGE OF HEART TRANSPLANTS, LIVER TRANSPLANTS, AND PANCREAS TRANSPLANTS. I WOULD LIKE NOW TO DESCRIBE BRIEFLY OUR CONSIDERATION OF EACH OF THESE TYPES OF TRANSPLANTS.

HEART TRANSPLANTS

A NATIONAL STUDY, FINANCED BY HCFA, IS NOW UNDERWAY OF ALL ASPECTS OF COVERAGE OF HEART TRANSPLANTATION UNDER MEDICARE. THIS INCLUDES:

1) THE ESTIMATIONS OF THE POTENTIAL NEED FOR HEART TRANSPLANTS;

2) THE SURVIVAL OF HEART TRANSPLANT RECIPIENTS;

3) THE POTENTIAL AVAILABILITY OF DONOR HEARTS;

4) THE COST OF PERFORMING HEART TRANSPLANTS;

5) THE REHABILITATION AND QUALITY OF LIFE OF HEART TRANSPLANT RECIPIENTS; AND

6) THE LEGAL AND ETHICAL ASPECTS OF HEART TRANSPLANTATIONS.

THE PROJECT STAFF INCLUDES AN INTER-DISCIPLINARY TEAM OF RESEARCHERS WITH EXPERTISE IN SUCH AREAS AS MEDICAL SOCIOLOGY, CARDIOVASCULAR MEDICINE, TRANSPLANT SURGERY, HEALTH ECONOMICS, CARDIOLOGY, POLITICAL SCIENCE, LAW, MEDICAL ETHICS, GEOGRAPHY, AND PSYCHOLOGY. AS PART OF THAT STUDY, MEDICARE IS PAYING FOR A LIMITED NUMBER OF HEART TRANSPLANTS AT SIX MEDICAL CENTERS PARTICIPATING IN THE STUDY. AT PRESENT, PLANS CALL FOR LIMITING PAYMENT TO 16 TRANSPLANTS. AT THIS TIME HCFA HAS PAID FOR NINE HEART TRANSPLANTS PERFORMED UNDER THIS STUDY.

THE STUDY IS SCHEDULED TO BE COMPLETED IN APRIL 1984, AND THE EVALUATION IS TO BE FINISHED THREE MONTHS LATER. WHEN THE ENTIRE STUDY PROCESS IS COMPLETED, HCFA WILL MAKE A DECISION REGARDING COVERAGE OF HEART TRANSPLANTATION UNDER MEDICARE.

LIVER TRANSPLANTS

AT THE END OF 1980, PHS RESPONDED TO A HCFA REQUEST FOR GUIDANCE ON LIVER TRANSPLANTS. THE PHS DETERMINATION WAS THAT LIVER TRANSPLANTS WERE STILL INVESTIGATIONAL. SINCE THEN, CYCLOSPORIN A, AN IMMUNOSUPPRESSANT DRUG, HAS BEEN MORE WIDELY USED, AND THERE IS SOME EVIDENCE THAT IT HAS HAD A FAVORABLE EFFECT ON LIVER TRANSPLANTATION. THEREFORE, IN APRIL 1982, HCFA REFERRED THE QUESTIONS OF SAFETY AND EFFICACY OF LIVER TRANSPLANTS TO PHS FOR REASSESSMENT.

HCFA ASKED PHS TO CONSIDER THE QUESTIONS OF MEDICARE COVERAGE IN TERMS OF SPECIFIC SUBGROUPS OF POPULATION. THIS WAS DONE BECAUSE THERE ARE SOME INDICATIONS THAT THERE ARE DIFFERING SUCCESS RATES IN LIVER TRANSPLANTS PERFORMED ON CHILDREN AND ADULTS, AND THAT RECENT "BREAKTHROUGHS" HAVE FAVORABLY AFFECTED ONLY THE SURVIVAL RATES OF CHILDREN.

PANCREAS TRANSPLANTS

ON OCTOBER 26, 1981, HCFA ASKED PHS FOR ITS RECOMMENDATIONS AS TO THE SAFETY AND EFFICACY OF PANCREAS TRANSPLANTS, ESPECIALLY WITH RESPECT TO ESRD BENEFICIARIES WHO ARE DIABETIC AND WHO HAVE UNDERGONE KIDNEY TRANSPLANTS.

CONCLUSION

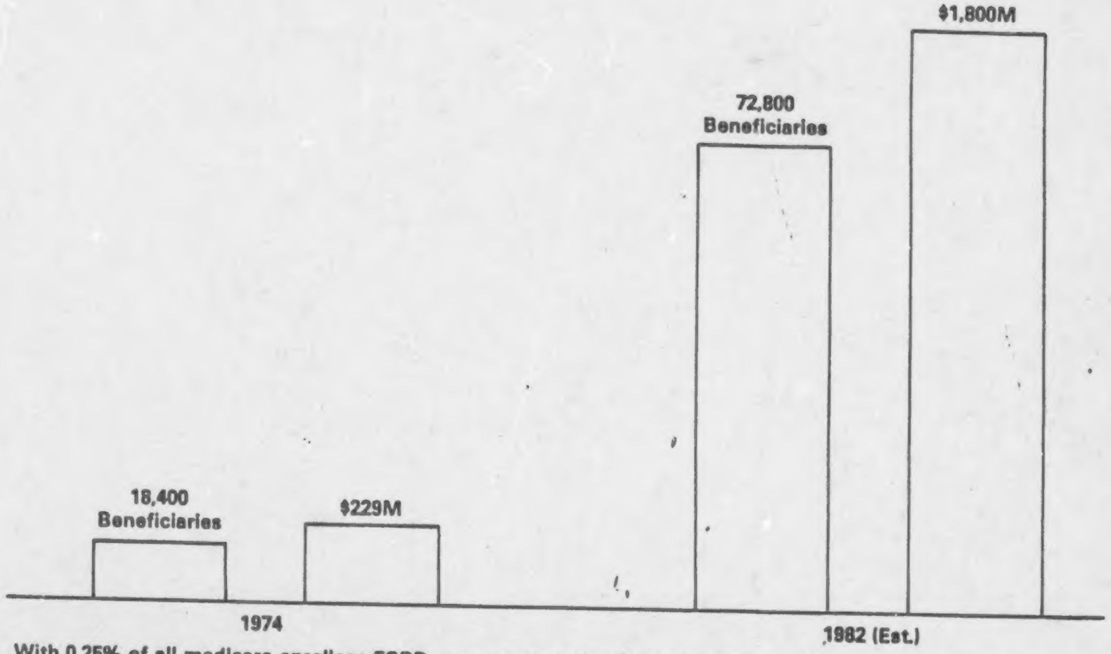
AS A NURSE AND FORMER HEALTH CARE PROVIDER, I WATCH WITH INTEREST AND EXCITEMENT THE TECHNOLOGICAL ADVANCES WHICH ALLOW US TO PROLONG LIFE, PREVENT OR RETARD MORBIDITY, AND PROVIDE ENHANCED QUALITY OF LIFE. AS ADMINISTRATOR OF HCFA, I HAVE THESE SAME CONCERNS IN MIND, BUT I HAVE AN ADDITIONAL RESPONSIBILITY AS GUARDIAN OF THE TRUST FUNDS SUPPORTING THE MEDICARE PROGRAM TO ASSURE THAT WE REIMBURSE FOR CARE WHICH IS REASONABLE AND NECESSARY AS REQUIRED BY THE LAW.

THOSE TRUST FUNDS ARE IN JEOPARDY IN FUTURE YEARS. OUR ACTUARIES PROJECT THAT THE HOSPITAL INSURANCE TRUST FUND COULD BE INSOLVENT AS EARLY AS 1990. WE WILL HAVE TO SLOW THE RATE OF PROGRAM EXPENDITURES OR INCREASE TAXES DRAMATICALLY IN THE NEXT DECADE IF WE ARE TO ASSURE THAT A PROGRAM CONTINUES TO BE AVAILABLE TO PAY FOR HEALTH CARE FOR THE AGED AND DISABLED. THE ADMINISTRATION'S HEALTH INCENTIVE REFORM PROPOSALS SUBMITTED WITH OUR FY 84 BUDGET ARE AN IMPORTANT STEP IN THIS DIRECTION. WE MUST ALSO CAREFULLY ASSESS NEW TECHNOLOGY AND WEIGH ITS BENEFITS AND COSTS CAREFULLY. I HAVE NO EASY ANSWERS TO THESE CRITICAL PROBLEMS, BUT I BELIEVE I WOULD BE REMISS IN MY RESPONSIBILITIES IF I FAIL TO MENTION THEM TODAY.

I FEEL VERY STRONGLY THAT TRUST FUND MONIES SHOULD ONLY BE SPENT ON PROCEDURES AND CARE GENERALLY ACCEPTED BY THE MEDICAL COMMUNITY AS SAFE AND EFFICACIOUS. INDEED, THE LAW DIRECTS THAT MEDICARE PAY ONLY FOR THOSE SERVICES WHICH ARE REASONABLE AND NECESSARY, AND THIS IS CRITICALLY IMPORTANT IN THESE DAYS OF ESCALATING HEALTH CARE COSTS AND POSSIBLE INSOLVENCY OF THE TRUST FUNDS. WE ARE THEREFORE CAREFULLY CONSIDERING, IN CLOSE CONSULTATION WITH OUR MEDICAL EXPERTS IN THE PUBLIC HEALTH SERVICE, DECISIONS ON THE SAFETY AND EFFICACY OF ALL TRANSPLANT PROCEDURES BEFORE PERMITTING COVERAGE AND EXPENDITURE OF MEDICARE TRUST FUNDS.

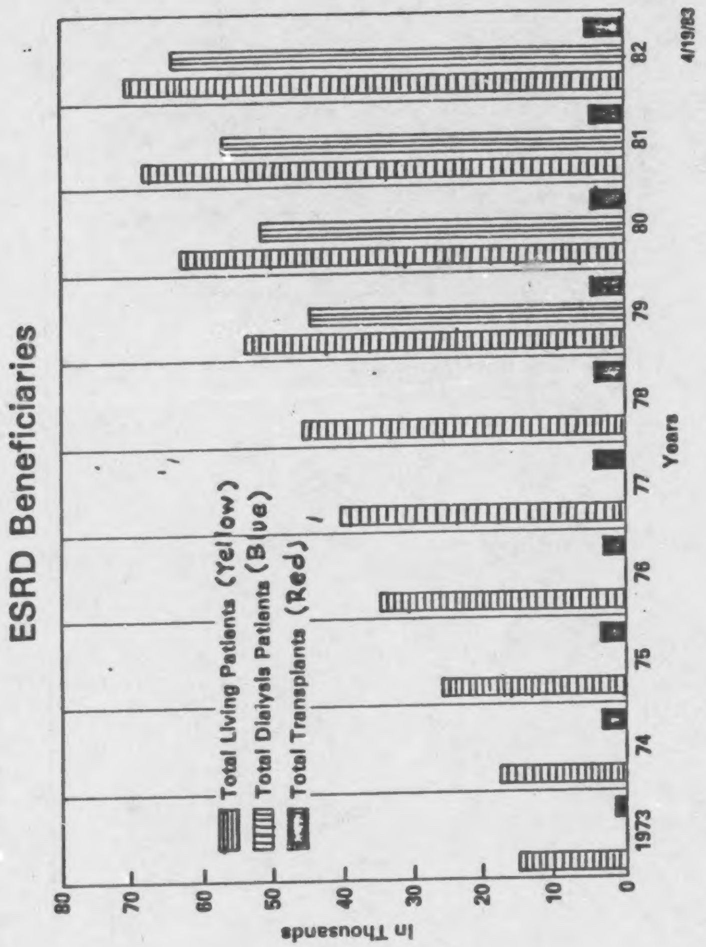
I LOOK FORWARD TO WORKING WITH YOU AND OTHERS IN THE CONGRESS AS WE LOOK CAREFULLY AT THESE IMPORTANT PROBLEMS, AND I WOULD BE PLEASED TO ANSWER ANY QUESTIONS YOU MAY HAVE AT THIS TIME.

ESRD Program Growth

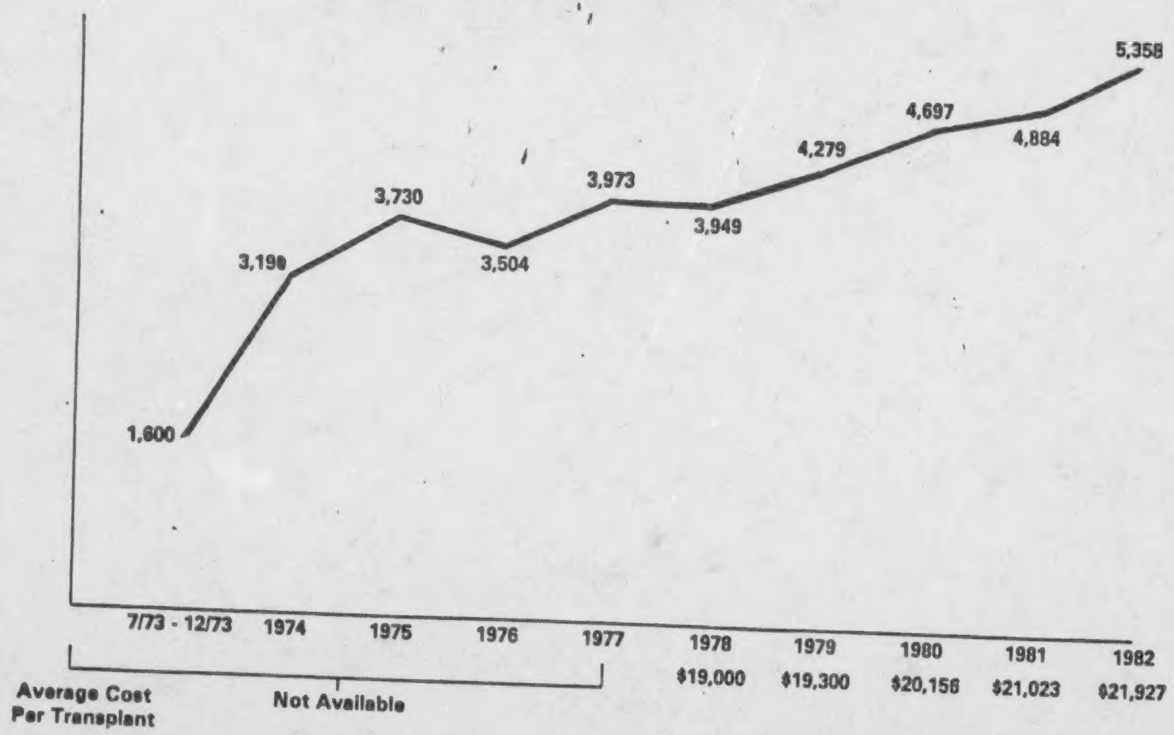


With 0.25% of all medicare enrollees ESRD now accounts for 6.4% of Part B payments and 3.7% of All Medicare payments.

4/19/83


ESRD Beneficiaries
In Thousands
80
70
60
50
40
30
20
10
0
Total Living Patients (Yellow)
Total Dialysis Patients (Blue)
Total Transplants (Red)
1973
74
75
76
77
78
79
80
81
82
Years
4/19/83

Transplantation
Number of Kidney Transplants
(Medicare and Non-Medicare)



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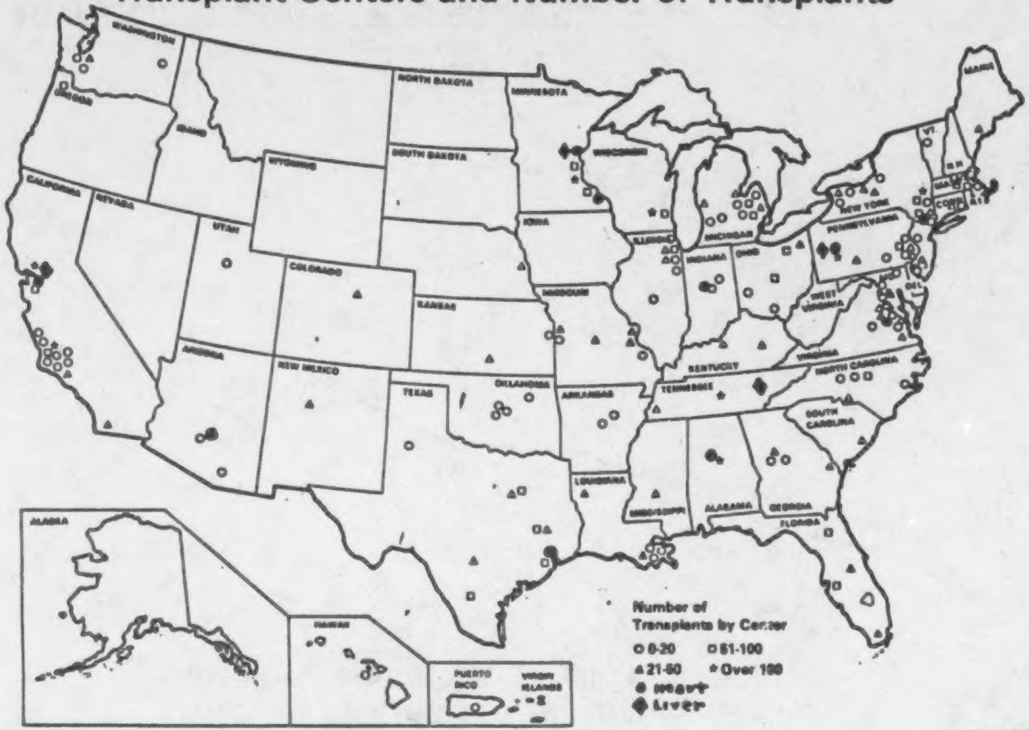
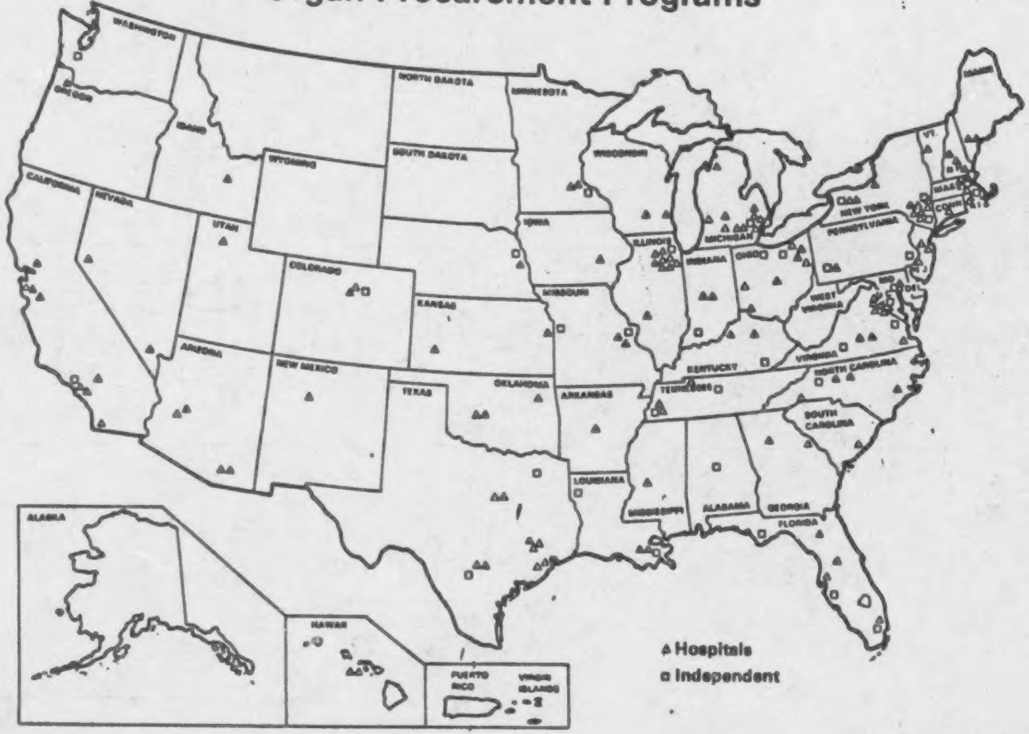
ESRD
Transplant Centers and Number of Transplants


WASHINGTON
OREGON
CALIFORNIA
NEVADA
IDAHO
UTAH
ARIZONA
WYOMING
COLORADO
NEW MEXICO
NORTH DAKOTA
SOUTH DAKOTA
KANSAS
TEXAS
OKLAHOMA
MINNESOTA
IOWA
MISSOURI
ARKANSAS
LOUISIANA
WISCONSIN
ILLINOIS
MICHIGAN
INDIANA
OHIO
KENTUCKY
TENNESSEE
MISSISSIPPI
ALABAMA
GEORGIA
FLORIDA
SOUTH CAROLINA
NORTH CAROLINA
VIRGINIA
WEST VIRGINIA
PENNSYLVANIA
NEW YORK
VT
N.H.
MAINE
MASS
CONN
R.I.
DEL
ALASKA
HAWAII
PUERTO RICO
VIRGIN ISLANDS
Number of
Transplants by Center
○ 0-20
□ 51-100
▲ 21-50
★ Over 100
● Heart
◆ Liver

4/19/83

Organ Procurement Programs


WASHINGTON
OREGON
CALIFORNIA
NEVADA
IDAHO
UTAH
ARIZONA
WYOMING
COLORADO
NEW MEXICO
NORTH DAKOTA
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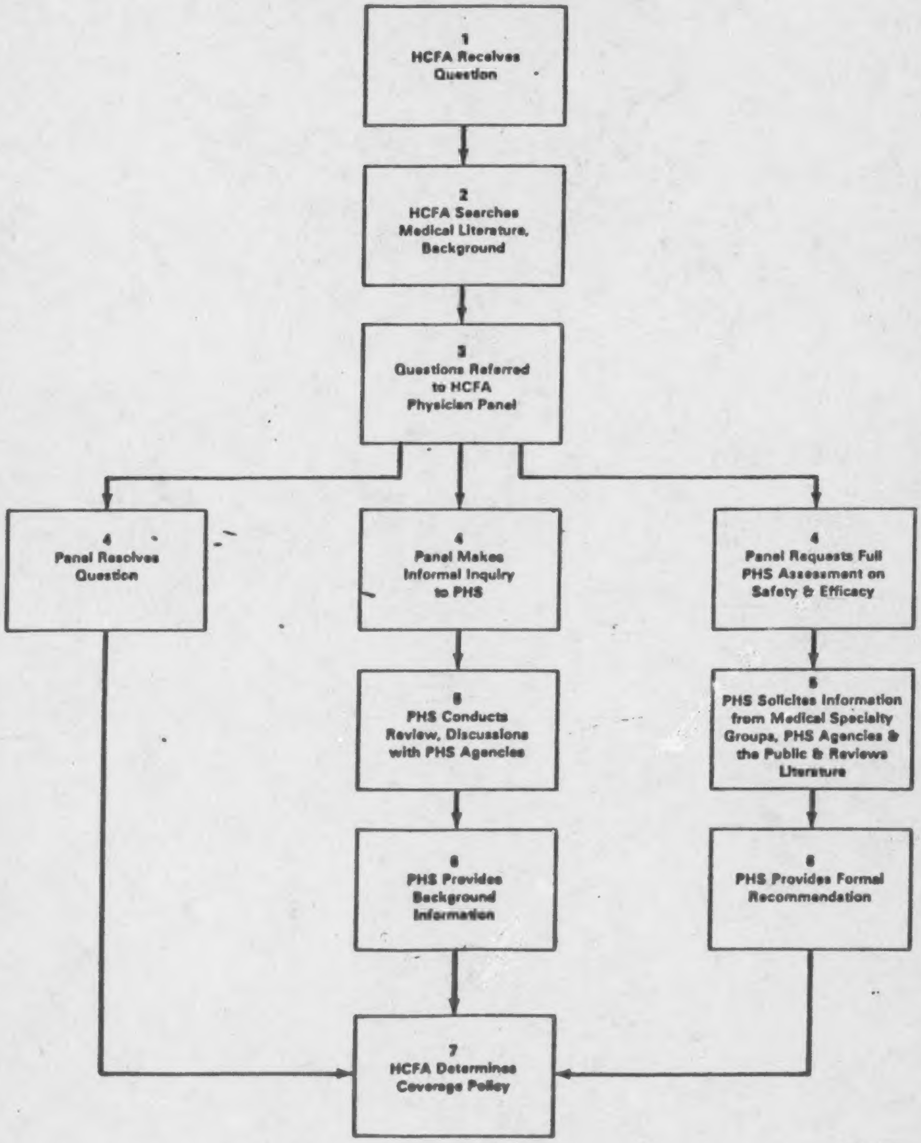
KANSAS
OKLAHOMA
TEXAS
MINNESOTA
IOWA
MISSOURI
ARKANSAS
LOUISIANA
WISCONSIN
ILLINOIS
MICHIGAN
INDIANA
OHIO
KENTUCKY
TENNESSEE
MISSISSIPPI
ALABAMA
GEORGIA
FLORIDA
SOUTH CAROLINA
NORTH CAROLINA
VIRGINIA
WEST VIRGINIA
PENNSYLVANIA
NEW YORK
MD
DEL
CONN
MASS
VT
MAINE
ALASKA
HAWAII
PUERTO RICO
VIRGIN ISLANDS
△ Hospitals
□ Independent

4/19/83

How Decisions Are Made Regarding Medicare Coverage


1
HCFA Receives Question
2
HCFA Searches Medical Literature, Background
3
Questions Referred to HCFA Physician Panel
4
Panel Resolves Question
4
Panel Makes Informal Inquiry to PHS
4
Panel Requests Full PHS Assessment on Safety & Efficacy
5
PHS Conducts Review, Discussions with PHS Agencies
5
PHS Solicites Information from Medical Specialty Groups, PHS Agencies & the Public & Reviews Literature
6
PHS Provides Background Information
6
PHS Provides Formal Recommendation
7
HCFA Determines Coverage Policy

4/13/83

Mr. **Gore**. Thank you, Dr. Davis.

Dr. Beary is our last witness on this panel, Acting Assistant Secretary of Defense for Health Affairs at DOD. Welcome.

STATEMENT OF JOHN F. BEARY III, M.D., ACTING ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS, ACCOMPANIED BY ALEXANDER RODRIQUEZ, M.D., MEDICAL DIRECTOR, O-CHAMPUS; AND ROBERT L. GILLIAT, ESQ., ASSISTANT GENERAL COUNSEL, MANPOWER AND HEALTH AFFAIRS, DEPARTMENT OF DEFENSE

Dr. **Beary**. Thank you.

Mr. Chairman and committee members, thank you for the opportunity to comment on DOD's policy on organ transplants.

The Defense Department operates 161 hospitals worldwide to serve some 10 million military personnel, retirees, and families. When military families cannot get their medical care in the Services' treatment facilities, the civilian health and medical program of the uniformed services, or CHAMPUS, shares the costs of care from civilian providers. So we are involved with organ transplantation both as a direct provider of care and as the operator of a health benefit plan.

Adriane Broderick, one of the children here last week, is awaiting a liver transplant. Because her father is a career member of the Armed Forces, we in the Defense Department are particularly concerned. As the father of two young children myself, I can well understand the anguish of her parents and grandparents.

Our Office of General Counsel has reviewed the legal situation pertaining to the case and has advised me that it is legally objectionable to pay for experimental medicines and surgery, until such time that medical researchers prove that a therapy is effective and that it is not more likely to harm the patient than to help.

Given the above restrictions, the issues before us are: No. 1, how does CHAMPUS determine policy on whether a therapy is experimental or standard?

No. 2, is liver transplantation itself experimental or standard therapy?

No. 3, what can we do to help Adriane Broderick.

Issue No. 1 deals with technology assessment for CHAMPUS. We accept the findings of three bodies. One is the Blue Cross Medical Policy Council, and that is because CHAMPUS was modeled after high-option Blue Cross in our 1966 authorizing legislation.

No. 2, the components of the Public Health Service—NIH, et cetera, but basically a Public Health Service opinion would be the one that we would go by.

No. 3, the AMA Council on Scientific Affairs. CHAMPUS itself is too small a program to afford the cost of duplicating the above programs. It would probably cost us on the order of $500,000 to set up a technology assessment unit capable of dealing with all the new advances in medicine and surgery, so therefore we rely on the PHS to give us that information and those judgments.

Question No. 2: Is liver transplantation experimental or standard therapy? Blue Cross said that it was still experimental at their

March 1983 health policy meeting after hearing testimony from various medical advisers.

The AMA Council on Scientific Affairs has not taken a position.

The Public Health Services will have an NIH consensus conference on liver transplantation this June, as Dr. Brandt indicated in his testimony. We will follow the PHS guidance that arises out of that process.

In summary, none of the above technology assessment groups have to date endorsed liver transplantation. So, for the time being, CHAMPUS must assume it is experimental.

Question No. 3: Is what can we do to help Adriane Broderick. As I mentioned, we cannot pay for the surgical procedure itself, for reasons mentioned above. However, we do pay for hospitalization and other expenses related to her illness.

As we have done in other experimental transplant cases, we will assist the family in fundraising techniques to deal with the balance. With Captain Broderick, for example, the CHAMPUS has provided guidance on fundraising, community resources, running an appeal, and managing an appeal account.

In the area of heart transplants, there are specific centers with research funds available, and our staff has frequently assisted with these arrangements. The Air Force has provided transportation to and from such centers under its aero medical evacuation program.

Military organizations such as the Wives Club and the Army Relief Association have invariably provided loans or gifts to cover sizable portions of the bills not covered by CHAMPUS or not discounted or forgiven by the civilian hospital or civilian surgeon.

Finally—and this does not appear in my formal statement there but is stimulated by reading the concerns in the transmittal letter from you and Mr. Skeen—I have asked for a review of the military hospital organ procurement policy, and the Health Affairs staff has this review under way.

We will be soliciting comment and advice from your committee, the voluntary agencies, and Dr. Koop's people, with the following outcome in mind—to generate an action item for the Defense Health Council so that we can, systematically bring our assets to bear on this problem.

We have 10 million beneficiaries in the military hospital system itself, 12,000 doctors and 161 hospitals. So I hope, by approaching this systematically, we can come up with a very reasonable program to contribute to the shortage of organs that has been described in the preceding hearings.

So, in conclusion, I will pledge my personal support to this effort and keep your committee fully informed.

Thank you.

[Prepared statement of Dr. Beary follows:]

STATEMENT OF

JOHN F. BEARY, III, M.D.
ACTING ASSISTANT SECRETARY OF DEFENSE
(HEALTH AFFAIRS)

Mr. Chairman and Committee Members:

Thank you for the opportunity to comment on DoD's policy on organ transplants. The Defense Department operates 161 hospitals worldwide to serve some 10 million military personnel, retirees, and families. When military families can't get their medical care in the Services' treatment facilities, the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) shares the costs of care from civilian providers. So, we are involved with organ transplantation both as a direct provider of care and as the operator of a health benefit plan.

Adriane Broderick, one of the children here last week, is awaiting a liver transplant. Because her father is a career member of the Armed Forces, we in the Defense Department are particularly concerned. As the father of two young children, I can well understand the anguish of her parents and grandparents.

Our Office of General Counsel has advised me that it would be legally objectionable to pay for experimental medicines and surgery, until such time that medical researchers prove that a therapy is effective and that it is not more likely to harm the patient than to help.

Given the above restrictions, the issues before us are:

1. How does CHAMPUS determine policy on whether a therapy is experimental or standard?
2. Is liver transplantation experimental or standard therapy?
3. What can we do to help Adriane Broderick?

TECHNOLOGY ASSESSMENT FOR CHAMPUS

We accept the findings of:

A. The Blue Cross Medical Policy Council (CHAMPUS was modeled after high-option Blue Cross in our 1966 authorizing legislation).

B. The components of the Public Health Service, including NIH, FDA, AND OHTA.

C. AMA Council on Scientific Affairs.

D. CHAMPUS is too small a program to afford the cost of duplicating the above programs.

IS LIVER TRANSPLANTATION EXPERIMENTAL OR STANDARD THERAPY?

A. Blue Cross said it is still experimental at the March 1983 Health Policy meeting.

B. AMA Council on Scientific Affairs has not taken a position.

C. Public Health Service (NIH) will have a conference on liver transplantation in June as Dr. Brandt indicated in his testimony. We will follow the P.H.S. guidance.

In summary, none of the above technology assessment groups have to date endorsed liver transplantation. So for the time being, CHAMPUS must assume it is experimental.

WHAT CAN WE DO TO HELP ADRIANE BRODERICK?

A. We cannot pay for the surgical procedure itself for reasons mentioned above. However, we do pay for hospitalization and other expenses related to her illness.

B. As we have done in other experimental transplant cases, we will assist the family in fund raising techniques to deal with the balance.

With Captain Broderick, for example, the CHAMPUS staff has provided guidance on fund raising, community resources, running an appeal, and managing an appeal account.

In the area of heart transplants, there are specific centers with research funds available; and our staff has frequently assisted with these arrangements. The Air Force has provided transportation to and from such centers under its Aero Medical Evacuation Program. Military organizations, such as the Wives Clubs and the Army Relief Association, have invariably provided loans or gifts to cover sizable portions of the bills not covered by CHAMPUS or not discounted by civilian hospitals.

Mr. Chairman, I hope that this clarifies the CHAMPUS position.

Thank you.

Mr. GORE. Thank you, Dr. Beary.

Dr. Koop, you said that you, as a pediatric surgeon, were quite familiar with biliary atresia, and you said that when a child truly has biliary atresia, there are only two alternatives, either transplant surgery or death.

Do you believe that transplant surgery, in the case of a child who will die without it, that the procedure is more likely to harm than to help the child?

Dr. KOOP. The immediate benefit would certainly be to the child's advantage. The thing that we do not know, sir, is what the long-term effects are.

We do not know, for example, how long a child must stay on immunosuppressant therapy. We know we are creating a problem because immunosuppression itself is a real concern to the Public Health Service.

We do not know what the carcinogenic activity is of the immunosuppressive drug cyclosporin A because we haven't used it long enough.

So, in the long term, I really could not answer that question, sir, as to whether it would be beneficial or whether it might, in the long term, be harmful.

Mr. GORE. Well, the child is going to die without it.

Dr. KOOP. That is true. There is no question about that, but we do hesitate before we take a stand to have some information about what we can advise people about the long-term concerns about cancer and immunosuppression.

Mr. GORE. Well, the child has a chance with the surgery. The child is going to die without the surgery. How can you say that it might be more likely to hurt than to help?

Dr. KOOP. Well, I think another aspect of this, sir, that has to be taken into account is the patient himself, how his biliary atresia has affected him, how wide or narrow a window you have to do this procedure, because all children with the same diagnosis do not die at the same rate; they do not have the some complications.

Given 100 such children, under normal circumstances, without any help, 50 percent die in the first year, 25 percent die in the second year, and then the remaining 25 percent go on. I had one child live, years ago, as long as 9 years. It seems almost impossible to do that without bile drainage, but nevertheless, it happened.

Mr. GORE. And then what happened?

Dr. KOOP. Then he died.

But it is very difficult to speak generically about all biliary atresia because the patient selection has to be very, very carefully done.

Mr. GORE. Do any of them live a normal life?

Dr. KOOP. No, sir.

Mr. GORE. They all die?

Dr. KOOP. They all die.

Mr. GORE. And we have figures that the transplant procedure is now effective in 70 to 80 percent of the cases where it is used. Do you have any reason to disagree with that percentage?

Dr. KOOP. No, sir; I only know what I hear from the transplanters.

Mr. **Gore**. OK, so we have two choices here. Without the surgery, 100 percent of them are going to die. That is correct, right?

Dr. **Koop**. That is correct, sir.

Mr. **Gore**. With the surgery, 70 to 80 percent will live. And yet the Government tells us they cannot decide whether or not the procedure is more likely to hurt than to help. That just doesn't make sense.

Dr. **Koop**. I don't think that we have told you we cannot decide, sir.

Mr. **Gore**. Well, let me refer you to Dr. Beary's statement. I am quoting from page 1.

> Our Office of General Counsel has advised me that it would be legally objectionable to pay for experimental medicines and surgery until such time that medical researchers prove that a therapy is effective and that it is not more likely to harm the patient than to help.

Why is there any doubt about the fact that liver transplants are more likely to help than to harm?

Dr. **Koop**. Let me answer that question, and then I will ask Dr. Brandt to expand upon it.

We have been aware of this, sir, for a long time, and the reason that there is a consensus conference is because we recognized that there was a need for a decision.

With liver transplantation, I think it is fair to say that the state of the art has moved along much more rapidly than is ordinarily the case in technology transfer to clinical medicine.

But, having planned a conference with all of these international experts who know much more than I do about this situation, I think it would be improper for me to make a statement flatfootedly now until that consensus conference has come to a close.

Mr. **Gore**. Now, there are some children that may well die between now and then, and this has been going on now for, what, 15 months?

Dr. **Brandt**. No, sir.

Mr. **Gore**. A year?

Dr. **Brandt**. It has been going on approximately a year. But I think that you have to consider that at this point in time, there is no clear definition regarding the selection of patients. There is no clear definition of what the time period ought to be. In other words, when should the liver transplant be performed? There is no clear criterion for the quality or the condition of the liver.

Let's not forget that in the case of a child receiving a liver transplant, one child dies, namely, the donor. The problem of trying to determine what the criteria are for that liver to be transplantable we still don't know the answer to many of these questions.

Our role in this, as we see it, is the issue of trying to determine the answers to some of those questions. Admittedly, there has been a lot of information that has accumulated in the last year, and we are fully prepared now, I believe, to go into that conference, to bring in all of the experts from around the world, to begin to determine the answers to some of these questions, so that we can come out with a series of recommendations that will be of the greatest benefit to the greatest number of people.

Mr. **Gore**. Well, Dr. Beary, let's talk about Adriane Broderick. Her doctors tell this subcommittee that she is going to die unless she has a liver transplant.

The facilities where the transplant will take place, hopefully, say they cannot perform it until her father's insurance plan agrees to pay for it. Her father, unfortunately, is on active duty with the U.S. military. I say unfortunately because if he had a private insurance plan, if he had one of most of the private insurance plans, his daughter's life could be saved. But he is covered as an active-duty military officer by CHAMPUS.

I had reason to believe, and the subcommittee had reason to believe, that in response to the letter that Congressman Skeen and I sent to the Secretary of Defense, DOD was prepared to change its policy. We were informally advised that such a change was under way.

However, you tell us this morning that such a change would be "legally objectionable," according to your Office of General Counsel.

Now, you tell us that the Army Relief Association and the Wives Clubs will have a fundraising drive and that you are going to give Captain Broderick advice on how to mount a public fundraising appeal in order to save his daughter's life. Yet you will not pay for the surgery.

You will pay for all of the care his daughter needs as she dies. Experts have told us that the costs of that care often far exceed the cost of the transplant procedure which can save her life.

I find your testimony extremely disappointing—extremely disappointing.

Dr. **Beary**. Perhaps I could respond to a couple of your concerns.

Mr. **Gore**. Yes, please do.

Dr. **Beary**. First of all, I think we have to see where we have some common assumptions. As we mentioned, the way title 10 is written and has been interpreted, we are precluded from paying for experimental surgery, and the testimony of the other witnesses has borne that out.

I would say, if that indeed is the barrier, as it seems to me and competent legal opinion to be, the action is in your branch of government. If you want to change title 10 to address experimental surgery, you need——

Mr. **Gore**. Now, wait a second. On what basis have you concluded that this is experimental surgery?

Dr. **Beary**. By the absence of a credible national body such as the three I have mentioned to come to a consensus or a conclusion about the matter.

Mr. **Gore**. You cite Blue Cross, and yet Blue Cross is reimbursing for these procedures. In fact, they are reimbursing, I believe, for more of them than anybody else.

Do you have those figures here? Hold on a second.

In Pittsburgh, out of 19 procedures, liver transplants paid in full, 11 of them were Blue Cross.

Dr. **Beary**. That contradiction can be explained in the sense that the national Blue Cross body, which discussed it at a conference in March, said that at this point in time they are still experimental. However, individual plans are able to do what they want to do, just as individual States under medicaid are free to do what they want to do, although PHS and HCFA, in 60 days, are setting up the conference to deal with the issue definitively.

Mr. **Gore**. After a year of talking about it.

Dr. **Beary**. June is within 60 days. I think that is a reasonable——

Mr. **Gore**. Well, she may not have that long to live. You understand that.

Dr. **Beary**. I have not been involved in her direct care, so I cannot comment on the specifics of her case.

Mr. **Gore**. What kind of advice are you going to give Captain Broderick on fund raising? Are the recruitment advertising people going to be called in?

Dr. **Beary**. Well, I think that is a rhetorical question, sir.

Mr. **Gore**. No, I am quite serious.

Dr. **Beary**. You may as well answer it yourself.

Mr. **Gore**. No, sir. I am quite serious. Have you got a plan to——

Dr. **Beary**. Yes, we have a serious plan.

Mr. **Gore**. And what does it involve? Public appeals?

Dr. **Beary**. I will have to supply details for the record. I don't have the details at my fingertips, but I certainly can supply that for you.

Mr. **Gore**. I wish you would supply those details for the record.

Dr. **Beary**. I will do that, sir.

[The information follows:]

If beneficiaries and their families indicate a desire, as have the Broderick's, to have a liver tansplant done on their child, CHAMPUS will share with them advice on fund raising and the location of possible research funds that it has collected through the years. The information consists of such items as types of community activities that have been found to be successful, how to set up and maintain a tax-free account and how to approach the media.

This assistance does not, however, ordinarily require the Department to incur any incremental costs. The services are generally provided by people whose jobs already include assistance with morale, welfare, and health related problems. These individuals are simply asked to add to their activities assistance to those who seek to take advantage of investigational medical procedures that are not covered under the health benefits provided to DOD beneficiaries.

Mr. **Gore**. I would like to explore this a little bit with you now. Are you going to have television commercials?

Dr. **Beary**. I will supply all the details for the record. I would not want to decide on the spot on a level of detail of that sort.

Mr. **Gore**. How much money do you expect to spend on the fund raising plan?

Dr. **Beary**. I have no additional information on the details beyond what I gave you. The letter from your committee did not imply that you were going to be interested in that level of detail.

Mr. **Gore**. Well, it is the only alternative for this child whose life is in danger at this point.

How much do you expect from the Wives Club?

Dr. **Beary**. Well, there is another alternative. If your committee wants to change title 10 and pass an appropriation for it, we are in business.

Mr. **Gore**. How much do you expect that he can raise from the voluntary fund raising drive?

Dr. **Beary**. Well, perhaps I could illustrate it with an example, with a recent heart transplant case we had in Arizona. CHAMPUS, as I said, can pay for any aspects of the illness that are reasonably related to the illness.

As you have heard from all of the witness, law precludes us from paying for the surgical fee itself or the operating room or anesthesia fee itself. However, we try to certainly give the patient the benefit of the doubt on anything where there is a judgment call, and in this particular case in Arizona that Representative Michael was involved in, they were able to raise enough funds so that there was actually a balance left in that particular case.

So I am not as pessimistic as you are about the efficacy of those things. Until Congress changes its guidance on this matter, in my branch of the Government, we have to follow the law as it is written.

One hundered four thousand dollars was raised in Arizona.

Mr. **Gore**. Are you going to provide assistance in mounting a public relations and fund raising drive for the other uniformed military personnel whose children are waiting?

Dr. **Beary**. Certainly. We will have a uniform policy and guidelines that will apply to all of the men. Anything we can do within our power, we will do. Obviously, our first interest has to be that of the beneficiary, but, as you well understand, there are laws that guide just exactly what we can do.

It is a complex issue. One would want to decide very carefully before deciding to have, say, a carte blanche thing on reimbursing for experimental therapies.

Mr. **Gore**. Well, I don't see it as particularly complex in this instance.

Dr. **Beary**. Well, do you agree it is experimental or not? I am not sure we are communicating on that.

Mr. **Gore**. Well, I want to get to that, but before I do, let me ask you, how many other children of uniformed military personnel covered by CHAMPUS are currently suffering from biliary atresia and in need of liver transplants?

Dr. **Beary**. I will have to supply that information for the record, also.

[The information follows:]

Mr. Chairman, I can only report on the number of families who have asked CHAMPUS to cost-share liver transplant operations.

Because the CHAMPUS program is designed to adjudicate and cost-share health care services provided to its beneficiaries, the only way that CHAMPUS can become aware that a beneficiary has recevied a service, or needs to receive a service, is when a claim is submitted for payment, or when a beneficiary inquires if a service is covered.

To date CHAMPUS is aware, through these two mechanisms, of requests for liver transplants for: 1. Adriane Broderick; 2. Aaron Polhemus; 3. Michael Rasdon; and 4. Frank Silcox, Jr.

Mr. **Gore**. We are informed that there are seven.

Dr. **Beary**. It is feasible.

Mr. **Gore**. It is feasible. And you will provide assistance in mounting a public fundraising drive for the families of all seven, is that correct?

Dr. **Beary**. Certainly, we will supply all patients with the same approach, same type of assistance we would give any other patient.

Mr. **Gore**. How many children of military personnel have already died because CHAMPUS refused to pay for the procedure to save their lives?

Dr. **Beary**. And the Congress refused to change title 10; to cover it. I don't have the answer.

Mr. **Gore**. Well, you keep inserting title 10; Dr. Beary.

Dr. **Beary**. What does your counsel say?

Mr. **Gore**. Dr. Beary, please let me conclude my question, if you would. You keep inserting title 10; but the word "experimental" I do not think can fairly be used to describe a procedure that has a 70- to 80-percent success rate.

The real issue here is how quickly the bureaucracies represented at the table can adjust to changed circumstances.

As Dr. Koop stated, the progress where liver transplantation is involved has been more rapid than is usually the case with new medical procedures. The introduction of cyclosporin A and the dramatic increase in surgeons' skills have jumped the success rate from the 30-percent range up to the 80-percent range in a very short period of time.

And yet the bureaucratic organizations that are charged with evaluating medical procedures have been slow to react. We are right now—well, let me give you an example. In July 1981, an editorial in the British Medical Journal, with which I am sure Dr. Koop and Dr. Brandt are familiar—the publication of the British Medical Society back in July 1981 published an editorial headlined "Liver Transplantation Comes of Age " almost 2 years ago.

It concluded as follows: "It gives a chance of excellent rehabilitation for patients with no other treatment available, and the operation is probably less costly then prolonged care of a patient dying of liver disease."

Now, that is almost 2 years ago, and the medical community has known this. It is fair to say that this is a more rapid advance. But to label it experimental in the spring of 1983 is just unreasonable.

Now back to my question, Dr. Beary. You don't know how many children of military personnel have died while awaiting this procedure—has your staff provided you with that information?—because CHAMPUS refuses to pay for it?

Dr. **Beary**. No, sir.

Mr. **Gore**. We have heard that there are at least two, and that they are currently suing the Department of Defense. Does your counsel have knowledge of ongoing lawsuits of that kind?

Dr. **Beary**. We have no knowledge of that.

Mr. **Gore**. All right; we will elaborate on that for the record and give you an opportunity to do so as well. We have heard that there are two children of active-duty military personnel that have died of biliary atresia, principally because they were unable to pay for the operation and get on the list, and the reason they were unable to get on the list is because the U.S. Government, the CHAMPUS program, was unwilling to pay for it.

[The information follows:]

Mr. Chairman, our counsel has no knowledge of any on-going lawsuits related to liver transplants.

Mr. **Gore**. Dr. Brandt—and I am just going to ask a couple more questions and then recognize my colleague and come back for another round—first of all, would you agree that this procedure, liver transplantation, has improved in its efficacy much more rapidly than is usually the case for new procedures?

Dr. **Brandt**. I think so—and I would not limit it just to liver transplants—largely because, I think, of the development of cyclosporin A.

As you pointed out, prior to cyclosporin A, the 1-year survival rates—and I think you need to continue to emphasize that the number of children that have had liver transplants over a prolonged period of time, in this country, largely prior to 3 years ago—was very small; so we really only know the survival rate for that short period of time. But that rate, as you point out, has increased dramatically. As you know, we received a new drug application for cyclosporin A from the sponsor in November 1982—that is 5 months ago—and we are in the process, in the final stages, of evaluating that drug to make it available.

So we are talking about the use of an experimental drug that has made, in large part, this dramatic change. I think it has moved rapidly; I agree with you.

Mr. **Gore**. It has been widely available for quite some time and is used in all of the centers doing the transplant surgery.

Dr. **Brandt**. Yes, as an investigational drug. That is correct.

Mr. **Gore**. Dr. Koop, you are known as a man of integrity and sensitivity, great attention to problems of medical ethics and the like. If you had a patient with biliary atresia, would you be reluctant to prescribe a liver transplant?

Dr. **Koop**. Well, I have been in that situation, sir, a number of times. I finished my active practice in March 1981. A lot of this has happened since then.

Mr. **Gore**. Yes.

Dr. **Koop**. But I would say that in the years that, say, Dr. Starzl first began doing this sort of thing, I must have had 20 patients that today might be considered suitable for transplant, and I only felt that two of those, because of their other medical conditions, were suitable for referral, and neither one of those did Dr. Starzl's team think were suitable for referral.

That is what I meant before, that you just cannot talk about liver transplants generically. There were about 20 children that never were even offered for transplant because of a decisionmaking process with a lot of medical expertise.

Mr. **Gore**. Well, let me rephrase the question, then. If the child's pediatrician and the consulting specialist told you that a liver transplant was indicated and had a good chance of saving the child's life, you certainly would not stand in the way of that child receiving a liver transplant.

Dr. **Koop**. Well, we still don't know the criteria, sir. Many times I have done myself, or referred elsewhere, patients to have things done upon them which were indeed experimental. The fact that something has come of age does not mean that it necessarily is now to the point where you can discuss every single case and say these are the criteria, this is what we expect, and this is how it will go. It is not just open and shut.

Mr. **Gore**. Well, for many of these children, it is.

With biliary atresia, you may receive benefit from another operation, as you know, introduced from Japan, the Kasai procedure. Are you familiar with that?

Dr. **Koop**. I trained Dr. Kasai, sir.

Mr. **Gore**. That is what I was getting at. [Laughter.]

I understand that it benefits only a small number of patients, correct?

Dr. **Koop**. That is true.

Mr. **Gore**. But those it benefits, it provides real benefit.

Dr. **Koop**. No, it really does not. I think the long-term results in Dr. Kasai's hands are perhaps the best of any place in the world. Two other Japanese surgeons have done not quite as well but almost as well. The results in this country seem to be sporadic.

But I have to tell you that there are many of us in this field who believe that there are different aspects of liver disease among Oriental children than among Caucasian children, which may account for the differences in result.

Mr. **Gore**. Would you say the Kasai procedure is experimental?

Dr. **Koop**. Oh, I think definitely.

Mr. **Gore**. Dr. Beary, is the Kasai procedure paid for by CHAMPUS?

Dr. **Beary**. Dr. Rodriguez?

Dr. **Rodriguez**. To our knowledge, it is not.

Dr. **Beary**. To our knowledge, it is not.

Mr. **Gore**. Well, to our knowledge, it is. Captain Broderick's daughter received the Kasai procedure, and it was paid for by CHAMPUS. It is also routinely accepted and paid for by private insurance carriers and by medicaid without question.

Dr. Koop, by what process was it determined that the Kasai procedure was acceptable and thus eligible for reimbursement?

Dr. **Koop**. Well, I can explain that to you, sir.

We have to start with a jaundiced baby. All children are born looking unjaundiced, but those who have problems that lead to jaundice develop it within the next 3 days. Some of these are medical reasons for jaundice, some due to hematological problems.

When you realize that you have persistent case of jaundice that is probably due to the obstruction of the biliary tract either inside the liver or outside of the liver, there is no definitive way to make that diagnosis without doing an operation.

At that operation, you might find a rare patient who has a remnant of a bile duct that could be hooked up to his intestine, and he would be essentially cured, barring unforeseen complications.

Then you have maybe three or four other options of things that could be done as a surgeon. One of those options would be the Kasai procedure. But when you talk about whether the Kasai procedure per se is paid for, in my own experience, I would put that down on my insurance form sent to the insurance carrier as exploratory laparotomy for the diagnosis of obstructive jaundice, and it might cover three or four different operations.

So you might ask this question in a way where the answer is "yes," they pay for a Kasai procedure, or you could ask it in a way where the answer is no, they don't pay for a Kasai procedure.

Have I made that clear? It is complicated.

Mr. **Gore**. It is complicated.

The process that you went through, Dr. Davis, is also complicated, the process for determining when something is approved.

Don't you think it is fair to say that your procedure for evaluating this new technology has been too slow?

Dr. **Davis**. No; I believe that our procedure has a great deal of integrity to it. We do move expeditiously. But we also believe that we need to take into consideration a number of factors which both the Surgeon General and the Assistant Secretary for Health have outlined. We rely very heavily on expertise from the Public Health Service.

Mr. **Gore**. Are you familiar with the analyses presented to the subcommittee 2 weeks ago showing that the cost of a lingering death, where patients with biliary atresia are involved, exceeds the cost of the transplant, so that you are not only allowing them to die; you are also wasting the taxpayers' money in the process. Are you familiar with those analyses?

Dr. **Davis**. I did read that material.

Mr. **Gore**. What was your reaction?

Dr. **Davis**. My own reaction in terms of the medicare program is that, again, it is still an experimental procedure, and the fact that one age group, as I indicated, may appear to benefit more than another one is one of the dilemmas that we are in. That is one of the reasons why we ask the Public Health Service to help us make a decision on coverage. It really involves the feasibility of establishing the criteria, because we don't want to be discriminatory, and yet, on the other hand, we know just from the experimental material that is already available that organ transplantation appears to be more useful for some than for others.

So it really becomes a question of where should it be performed, if it should be performed, and upon whom in terms of safety and efficiency.

Mr. **Gore**. One more question. Dr. Beary, are you familiar, just isolating the child population for a moment, are you also familiar with the studies indicating that by allowing these children to die, you are simultaneously wasting money?

Dr. **Beary**. I haven't reviewed that for the basic reason that that data would have no impact on any decision I make. If the PHS approves this as standard therapy, I will cover it. I just cannot afford one-half a billion dollars to do my own technology assessment.

Mr. **Gore**. Where do you get the figure of one-half a billion dollars?

Dr. **Beary**. Well, that is about what it would cost DoD to duplicate the PHS health technology assessment setup, because, of course, we wouldn't do it just for——

Mr. **Gore**. Do you rely on Dr. Davis?

Dr. **Beary**. Well, Dr. Brandt, I believe, speaks for the head of the PHS.

Mr. **Gore**. Ok; well, Dr. Brandt, are you familiar with the analyses that show that where children are involved, leaving aside Dr. Davis' adult population for a moment, are you familiar with the studies showing that where children with biliary atresia are involved, by allowing them to die and refusing to pay for the transplants, you are also wasting the taxpayers' money at the same time?

Dr. **Brandt**. I have seen the data that was presented to you, sir, and am aware of that. However, at the present time, we do not take costs into account in determining whether or not treatment is of general applicability. If we did that, then, of course, that would quickly lead to a ceiling, and we would not evaluate high-priced technology. We will not be taking the cost of the procedure in to account in trying to come to this decision.

Mr. **Gore**. Well, I am going to cool off and think up some more questions while I recognize my colleague. [Laughter.]

But what we have here is an absolutely absurd situation, and it is very frustrating. Most all the private insurance companies recognize that this is no longer an experimental procedure. Most of them are reimbursing for it.

We have testimony showing that there is a 70- to 80-percent success rate with these procedures. We have testimony showing that it is cheaper to save their lives and go forward with the transplant than it is to pay for all the care needed during a lingering death, which you presently approve.

And yet the Government bureaucracies represented here absolutely refuse to recognize what is obvious to the medical experts in the field, and it is extremely frustrating. That is a slow, slow process that is cranking along toward the consensus conference in June, and then there will be an evaluation. It has been going on for 1 year already. And, in the meantime, these children need the money, and in its place we have the, I think, bizarre spectacle of the Defense Department providing public relations guidance to mount public fundraising drives for the children of the military personnel that need these procedures to save their lives. There is something bizarre about that.

Dr. **Brandt**. Mr. Gore, if I could comment 1 second on that. You have the testimony of a limited number of people thus far. You made the statement that medical experts agree that this is a standard procedure.

We are bringing in people from all over the world who have great experience in looking at this whole issue from the ground up. I don't think it is fair to say that, on the basis of the testimony before this subcommittee, you can conclude that all of medicine will agree with that.

Mr. **Beary**. I would reinforce Ed's comment if I could. If one listens only to advocates of a procedure, it is not surprising you get a unanimous endorsement. But there are some people who will be heard from at the NIH conference who are skeptical. I would not want to characterize their outcome or findings, but there have been questions raised about the immunosuppression. The heart transplant literature, as you probably have been following, shows that there may be Kaposi's sarcoma and AIDS-like illnesses showing up——

Mr. **Gore**. Look, speculation about possible complications later in life as a result of immunosuppression is not of that much relevance to a child that is going to die very soon without the procedure in question.

And to say that we have only heard one side, how do you explain the conclusion almost 2 years ago by the British Medical Society?

Dr. **Brandt**. Well, you quoted from an editorial written by an editor of that journal. That is correct.

Mr. **Gore**. By the Journal of the British Medical Society.

Dr. **Brandt**. That is correct, yes.

Mr. **Gore**. Congressman Skeen?

Mr. **Skeen**. It is about time to give our chairman a little rest here.

Mr. **Gore**. Yes.

Mr. **Skeen**. He is becoming overwrought. [Laughter.]

Aren't you glad you are here today? [Laughter.]

I want to turn this around a little bit and let's take another tack. I think that several of the questions that were asked earlier would give a good indication that maybe it is time for us to sit here and listen, rather than ask all these great questions, and I am not being critical. I think that what the chairman has brought out has been very significant, good questions, and it goes to the heart of the problem.

We are all displaying a great compassion for this problem, and I don't think there is a person in this room that can sit back there and look at that child that is in the back of the room doing the crying a while ago and not feel a very strong compulsion to do everything possible to make modern medical technology arailable to all those in need. But there are ways to do it.

I want to start with Dr. Beary. I really have a little problem with the statement about legally objectionable. Can you explain to me what the Office of the General Counsel was talking about, in specifics?

Dr. **Beary**. If it would be agreeable, I might let Mr. Gilliat address that himself, since he was involved in the review of that issue.

Mr. **Skeen**. I would like very much to hear it. What do you mean by legally objectionable, and at what point do we reach the point of knowing that this is an effective procedure and it is no longer experimental. I think the two are tied together in the same statement.

Go ahead, Mr. Gilliat.

Mr. **Gilliat**. Yes, I will attempt to explain it.

The Department of Defense is bound, of course, by its own regulations in implementing the rather broad language of chapter 55 of title 10, which authorizes CHAMPUS.

Those regulations prohibit payment for those kinds of procedures which are labeled experimental. The definition of experimental includes those procedures which are investigational.

The question then naturally follows, Why can't the regulations be changed? Could they be changed in a manner that would permit this?

In determining whether a regulation can be modified to include a procedure, we look to the high-option benefit Blue Cross available under the Federal employees health program. It is our understanding that under the high-option Blue Cross plan for Federal employees, liver transplants are not paid for.

Therefore, we have no legal authority, by reason of the legislative history of the 1966 amendments of chapter 55, which serves for us as a touchstone in determining the legality of what we do and what we provide, that is, the provisions of that high-option plan. Does that explain it, sir?

Mr. **Skeen**. That gives me a better idea.

Now, what would be your recommendation to us? This is your chance to tell the legislative body. You know, I have a deep-seated suspicion that a lot of the times when we jump on the regulatory agencies, part of the problem lies right here in Congress. We talk about you being slow in responding to a problem. Take a look at us.

What would you recommend insofar as regulations—I think Dr. Beary alluded to chapter 55 of title 10? What changes would you need in title 10 to facilitate CHAMPUS' response to organ transplants?

Dr. **Beary**. Basically, it would need to be an amendment that would say "experimental medicines and surgery are covered."

Mr. **Skeen**. Go ahead and just cover them?

Dr. **Beary**. Yes.

Mr. **Skeen**. In other words, do away with the experimental classification insofar as organ transplants are concerned.

Dr. **Beary**. Cover everything that people want to make a case for.

Now, the hazard of that is, just to list some things that had advocates at one time but fell out of favor, you may recall the internal mammary artery revascularization of the heart, where they took an artery and tried to restore circulation of the heart before the coronary bypass that we use now came into being. There was irradiation for enlarged tonsils and adenoids, which later turned out to cause cancer of the thyroid.

In today's issues, we have DMSO for arthritis and laetrile for cancer. So it is a very controversial area that one would be getting into, and one would want to approach it carefully. But that would be the authority we would need to be able to compensate for things before one of the national bodies such as Public Health Service makes a determination on it.

Mr. **Skeen**. Dr. Beary, what if you reduced and focused more on the types of surgery, those that the experimentation—say, limiting it to various types of organ transplants that you indicate rather than those that are rather highflown and still very much experimental?

Dr. **Beary**. Well, I wonder if I might suggest an option here.

Mr. **Skeen**. Sure.

Dr. **Beary**. Possibly, given what the NIH mission is, to advance science, and so forth, maybe it would make more sense to fund fully a few regional centers. There are only two or three places in the country, for instance, doing liver transplants.

If it were the desire of Congress to do more in this area, rather than proliferate the technology to areas where people—I mean, surgery is like anything else: If you don't do a lot of it, you don't get too good at it. And so it might make sense to keep it in those centers where there is a reasonable track record, but just be sure the funding is there to take care of whatever demand for whatever particular category of illness it was the desire of Congress to cover, be it livers, hearts, or what have you.

But the NIH would seem to be a mechanism in place already, if the funding were provided to be able to provide those services until science had made a determination on whether it had passed from experimental to standard therapy.

Mr. **Skeen**. Do you have some idea of the level of funding?

Dr. **Beary**. I do not; I think that would probably be a question that Dr. Brandt or HCFA might have an order of magnitude for the Nation's needs in that area.

Dr. **Brandt**. Well, if you are talking only about organ transplants, sir, that is one kind of question. If you are talking about assessment of——

Mr. **Skeen**. Let's just say organ transplants.

Dr. **Brandt**. Well, I do not know. I can certainly supply the information to you about the total costs that we are undergoing to evaluate these.

Mr. **Skeen**. I would be very interested in having that for the record.

[Material to be supplied follows:]

In the area of liver transplants, PHS estimates that it will cost approximately $100,000 to conduct an assessment. This includes the cost of the NIH consensus development conference (approximately $85,000) and the staff time of the Office of Health Technology Assessment of the National Center for Health Services Research (approximately $15,000). This, of course, does not take into account the cost of developing the data or the research which was used in the evaluations.

Mr. **Skeen**. I share the chairman's concern, too. I think there is an irony in the situation that we are willing to finance under various programs—but I can understand how we got in that position—those that are terminal, which are far more costly than just the transplant technology.

But until the Congress of the United States helps change the regulations, there is not a whole lot that you can do with it and stay within the guidelines. Am I mistaken?

Dr. **Beary**. That is an accurate reflection of the Defense Department's position.

Mr. **Gore**. Will my colleague yield?

Mr. **Skeen**. Surely.

Mr. **Gore**. The difference between the decisionmaking process in the administrative branch and in the Congress, I think, is profound.

In writing the laws, we have to use categories like "experimental," and then rely upon the experts in the administration to come up with an accurate definition, with an accurate judgment, on what is experimental and what is not.

Now, if they were incapable of doing so, then, in a case like this, for example, we could write specifically in, "Liver transplants are no longer experimental." But what is so frustrating is that the machinery and the process for deciding when something is no longer experimental in the light of dramatic new advances, like cyclosporin has made possible, if that does not proceed in an expeditious fashion, you get this kind of intolerable result that we have here today.

So the real upshot of this hearing ought to be a revamping of the procedures by which the executive branch decides what is experimental and what is not. Clearly, we have a procedure here—in my view, it is clear—that is no longer experimental, even if it is still labeled such.

Mr. SKEEN. I agree with you, Mr. Chairman, and what I am trying to get from these folk today is suggestions to us on how you change that procedure, because if I were an administrator sitting out there today, and I went to my general counsel, which most of you have to rely on, and that counsels says, "You can't do that," then the old armadillo complex comes into play, and you roll up in a ball and make sure that you are not going to get shot with an arrow, particularly from congressional groups, because we are just as happy to expedite your work as we are to impede it.

Maybe that is part of the problem, that we have not given you the flexibility. That is, how do we build some kind of sanity into this system so that the bureaucracy can react as administrators?

I agree with the chairman; you are supposed to have that kind of determination. But once again, knowing how the procedure works, once you arrive at a new technology and a new technique and a whole new area, you rely on your counsel, as far as I can see, and this is, I think, the case here, Dr. Beary, and I don't know whether Dr. Koop, Dr. Brandt, and Dr. Davis feel the same way.

Go ahead.

Dr. BRANDT. Congressman, could I address that for a moment?

Mr. SKEEN. I would like very much to hear you.

Dr. BRANDT. There are several aspects. In the first place, I would like to point out that CHAMPUS has decided to rely upon three expert bodies in this country for decisionmaking. None of those three has yet declared that this procedure is not experimental.

Second, in this country, we have no defined accepted process for assessing new medical technology except devices and drugs which go through the FDA as a regulatory agency to determine that drugs and/or devices are both safe and of value.

The Public Health Service's responsibilities in this area are limited to determining for medicare. Let me again emphasize that medicaid can pay for liver transplants right now in any State that opts to do that. In fact, a number of States, or some States, at least, have determined that they will pay for it.

Mr. SKEEN. As a matter of fact, that has become almost the normal procedure.

Dr. BRANDT. I don't know precisely how many States will pay, but there are some notable examples that will not.

But they do not wait to depend upon any kind of official determination that it is experimental or nonexperimental.

I do not argue with the fact that our process for looking at technology assessment needs reexamination. To that end, over 1 year ago, we convened a meeting involving professional societies, insurance carriers, and other groups to look at that whole question, and then went with the results of that to the Institute of Medicine. We have asked IOM along with other sponsors, including the insurance carriers, professional societies, and others, to look at the issue.

We are assisting, as well as HCFA, in their look at the whole process for technology assessment in this country outside of drugs and/or medical devices. They have a committee which is functioning to look at the issue.

The first question is, Who ought to do it? My own view is that this is not really a Federal responsibility. This is a private sector responsibility, but one that the Federal Government should certainly participate in, because we have a fairly major stake in the outcome of it. I have no disagreement that the process is not perfect I certainly would endorse that, and I have said so repeatedly. I think steps are under way to solve that problem.

But, at the present time, with respect to the Public Health Service's determination, medicare is rarely liable to pay for a liver transplant in a child. Indeed, that is a State decision, and States have the right to do that right now.

Mr. SKEEN. Let me ask Dr. Davis a question in that connection. Our focus has been on Captain Broderick's family's situation. Is there no other way, other than CHAMPUS, if a person is in the armed forces, that they cannot utilize medicaid or some other program to be funded for transplants?

Dr. DAVIS. I am really not familiar with the other resources that would be available in the private sector. Clearly, the medicaid program is a State program that does depend upon one's income level for eligibility.

My assumption would be that there probably would be no States that would have an income level determination that would encompass armed services employees. However, some 30 States do have what they call a medically needy program, which does mean that if medical expenses cause you to spend down to a certain point, you would then become available for medicaid benefits. So I think it would probably be within the private sector where the help would be.

Mr. SKEEN. Within the private sector. So then, you are not precluding the members of the armed services, because they have chances available to them; they still are eligible for other private sector assistance?

Dr. DAVIS. I am not an authority on the military component, so I really should not speak to that.

Mr. SKEEN. Well, after having members of the armed services on food stamps, I don't know why we cannot get them declared eligible for further programs.

Mr. GORE. Get a tin cup with some captain's bars on it.

Mr. SKEEN. Yes.

Mr. Chairman, thank you. That is all.

Mr. GORE. Back to these three things that CHAMPUS relies on that you referred to, Dr. Brandt. One of them is the AMA Council on Scientific Affairs. It has not looked into this, has it?

Dr. BRANDT. Not to my knowledge.

Mr. GORE. So you are not relying on them, or CHAMPUS is not relying on them, for a conclusion that the procedure is experimental, because they have not taken a position.

Dr. BRANDT. They have not taken a position.

Mr. GORE. All right. Now, Blue Cross, the individual Blue Cross plans, are reimbursing for these procedures. Many of them are.

Dr. BRANDT. Some of them are; that is correct.

Mr. **Gore**. And in the leading transplant center, they are reimbursing for more of the procedures than anyone else. Right?

Dr. **Brandt**. I presume. I am not familiar with the data on that.

Mr. **Gore**. But you are relying on them for the conclusion that CHAMPUS should not reimburse.

Dr. **Brandt**. I don't run CHAMPUS. I have to let the Department of Defense decide what they are going to rely on. I was simply pointing out that CHAMPUS has opted to rely on three different bodies. The Public Health Service has not yet made a decision. We have not taken a position, if you want to look at it from that standpoint, and will when the data is all available and has been reviewed by experts.

Mr. **Gore**. And the third source of advice and guidance is the Public Health Service, which you have responsibility for, correct?

Dr. **Brandt**. That is correct. Yes, sir.

Mr. **Gore**. OK. Why has it taken a year to address this question?

Dr. **Brandt**. Well, it takes a fair amount of time to do three things. One is that we held in June last year a 1-day conference and brought in experts from around the country, and some from overseas, to try to determine—the process that we follow is first to invite all—to publish in the Federal Register a notice that we are looking into it, to invite all relevant scientific societies to provide us with any information.

At the same time, we held a 1-day conference with experts in June of 1982, with experts from around the world, to try to determine whether or not the data were adequate to make a judgment. They determined it was not and that, therefore, a consensus conference was indicated.

In order to get the best minds that we can get from around the world, we have gone through a process of defining the questions on the basis of the data that we have, collecting the kind of information necessary. One of the key elements, don't forget, is cyclosporin A, and at the time that all of this planning was going on, we did not even have a new drug application with respect to that agent. Therefore, we needed the kinds of studies that the sponsor was carrying out in order to try to determine those things, since that drug was key.

So we are now planning on having this conference; it has been scheduled in June. It is on everybody's schedule and will be held at that time. Now, if you ask me, could we have shortened that a month, I am not going to sit here and say yes or no. I am sure that we might have done that with 20/20 hindsight, but at the time we moved in a reasonable fashion based on the knowledge that was available.

Mr. **Gore**. Dr. Beary, does DOD ever conduct clinical trials?

Dr. **Beary**. We participate in cooperative trials with NIH. Our large centers like Walter Reed, for instance, would likely have clinical research projects going, fitting the description you are applying there.

Mr. **Gore**. If you consider this procedure experimental, have you considered a clinical trial program encompassing the seven or so children that need the procedure, covered by your plan?

Dr. **Beary**. Our transplantation expertise tends to be in bone marrow and kidney areas. To my knowledge, we do not have people who approach Dr. Najarian and Dr. Starzl in ability to deal with the complex area of liver transplantation.

Mr. **Gore**. And you couldn't fashion a clinical trial involving a population that received treatment from physicians other than military doctors?

Dr. **Beary**. If the Committee would like me to do so, I can inquire as to what the possibilities are to pursue that.

Mr. **Gore**. Yes. If you could get back to us on that, it might be a way to get this child an operation.

Congressman Volkmer?

Mr. **Volkmer**. I have no questions.

Mr. **Gore**. We have a vote on in the full committee. It is just down the hall. I do have a few more questions, and I hate to strain your patience and indulgence, but if you would permit us, we would like to adjourn for just 5 minutes, and then we will come back and finish up this panel.

[Short recess taken.]

Mr. **Gore**. The subcommittee will come back to order.

Without objection, I would like to put into the record a letter the subcommittee has received from a Sergeant Frank W. Silcox, who is stationed at Cecil Field. He is a Marine stationed in Jacksonville, Florida, whose son is 18 months old, who needs a liver transplant. He was told by CHAMPUS that the procedure was experimental.

He writes in his letter that he contacted The White House, and a Mr. Batten at The White House wrote to Children's Hospital in Pittsburgh stating that CHAMPUS should cover the operation. That is a quote. Quoting further: "Now we are confused on whether the operation is covered or not covered."

[Material to be supplied follows:]

3306 Green Street
Jacksonville, FL

April 21, 1983

Rep. Albert Gore, Jr., Chairman
Subcommittee on Investigations and Oversights
Committee on Science and Technology
822 House Annex #1
U.S. House of Representatives
Washington D.C. 20515

Dear Rep. Gore

I am a career Marine stationed at Cecil Field, Jacksonville, Florida. I have a son 18 months old in need of a liver transplant. As the operation is not available at the Naval Hospital my son has been referred to civilians at Children's Hospital , Pittsburgh, Pennsylvania. My major problem now is the financial aspect of the surgery.

I have spoken to Mrs. Glover, the Champus representative at NAS Jacksonville. She advised me that the surgery is considered experimental and not a covered option under the Champus program. She suggested I contact the Champus office in Colorado. I spoke with Navy Lt. Miller in Colorado on April 8 or there about. He said Champus does not cover liver transplant surgery or any hospital stay in regard to transplant surgery.

Since the surgery is costly, approximately $70,000 to $150,000 and I am an active duty Marine with medical services provided by the government, I do not have any private hospital insurance program or ant other means to pay for the surgery.

We have contacted Children's Hospital in Pittsburgh, Pennsylvania and have thus contacted Michael Batten, aide to President Reagan. Mr. Batten wrote to Children's Hospital stating that Champus should cover the operation.

Now we are confused on whether the operation is covered or not covered. We have asked help and direction from our friend, Retired SeniorChief John Clark III, and he has established a trust fund for our son through the Greater Jacksonville Community Foundation. He is currently working on procuring the necessary jet transportation and other fund-raising drives.

Attached is a copy of a letter I have written to President Reagan requesting any help and assistance he can offer. Is there some way to revise the current Champus program and help us help my son and all other servicemen who may one day find themselves in similar dire straits?

Sincerely,

Frank W. Silcox, Sgt.

Mr. **Gore**. Have you been in contact, Dr. Beary, with the White House about this matter?

Dr. **Beary**. No. Mr. Batten never called to discuss the matter with me.

Mr. **Gore**. All right.

Dr. Brandt, you talked about the CDC pilot study on how to increase donor awareness.

Dr. **Brandt**. Yes, sir.

Mr. **Gore**. First of all, just a technicality. I said in my statement that it was a ninefold increase that the program produced, and you took issue with that and said it was a threefold increase. Let me just clear that up for the record.

In the base year, the year before the program went into effect, there were 10 kidneys retrieved. Two years later, there were 88 kidneys retrieved; 3 years later, 90 kidneys retrieved. That appears to be a ninefold increase.

Dr. **Brandt**. The information I have was that in the base year there were 30 kidneys retrieved, and then it went to—I don't think it is really—I mean, the facts are that it increased dramatically. The information that I received from CDC indicated 30, then 88, and so forth.

Mr. **Gore**. All right, fine. But it was a success, right?

Dr. **Brandt**. Yes, sir. It was a success; no question about it, for kidneys. I would like to point out that whether or not that is applicable to other organ systems is, at the moment, not known, in part because with kidneys you do have an organ preservation time that exceeds that of both liver and heart. It is clear that this system worked. We have made that information widely available through the transplantation literature and have provided technical assistance and will provide technical assistance to any organ procurement group that wishes to take advantage of that.

Mr. **Gore**. Yes. Well, I think the figures are complete enough in the study to show that the longer survival time of excised kidneys is not a sufficiently large variable to diminish the applicability of the conclusions to other organs as well.

Why was this study terminated?

Dr. **Brandt**. Well, this study, which was done some years before any of us at this table were around, was intended to be a demonstration. It was intended to demonstrate to the medical community at large, steps that could be taken. When they had successfully demonstrated the steps that could be done and made the information widely available, it was then the goal that those organ procurement groups that are currently in operation would pick up those techniques and run with them.

Mr. **Gore**. Yes. The original plan was that if the pilot study was a success, the CDC would move into five regional demonstration projects. Everyone who has looked at these problems agrees that donor awareness is the key to solving the problem. The problems of financing will eventually be solved. They should be solved sooner rather than later, and we have been talking about that. The efficiency of the donor procurement network is important, but the key to the problem is donor awareness, and here the CDC demonstrated either a threefold or a ninefold increase in organ availability, and they were going to expand it into five regional demonstration projects, and the demonstration projects alone were calculated to save the ESRD program substantial sums of money.

And yet, Dr. Davis, HCFA declined to continue the demonstration projects. Why?

Dr. DAVIS. Well, as Dr. Brandt indicated, that study was completed and that request was asked of a different administration. I really cannot second-guess what a previous administrator or the previous administration felt in relationship to why they did not wish to continue the demonstration projects.

Perhaps it was because there was a request for $3 million for five sites. I simply do not know. When I first became involved in the end-stage renal disease program in March 1981, I soon became aware of the necessity for the Department as a whole to develop what I thought was an overall strategy relative to all of the end-stage renal disease program. Transplantation, prevention, and research all needed to be considered. I asked one of my senior staff to chair an interdepartmental task force that would look broadly at a number of these issues That task force worked very diligently for a number of months and brought forth a report in April 1982 which I think both Dr. Brandt and I have found very helpful. We proceeded to try to implement some of the suggestions as a result of that task force and one of them has been, of course, the whole area of transplantation.

Mr. GORE. Now, do you have an Office of Special Programs?

Dr. DAVIS. No, I do not. There was one.

Mr. GORE. Where is the Office of Special Programs making recommendations for supporting and fostering kidney transplantation?

Dr. DAVIS. There used to be an Office of Special Programs within HCFA. That particular component was phased out and the individuals were transferred into either the operations or the policy components because I felt that it was important to have them functioning within the total system.

Mr. GORE. Well, Dr. Davis, in July 1981, the Office of Special Programs made recommendations to you about fostering kidney transplantation, and they revived the recommendation that the CDC demonstration projects go forward, along with increased support of transplant coordinators.

That is not the last administration; that is this administration.

Dr. DAVIS. No. That was a recommendation to me, Mr. Gore.

Mr. GORE. That was a recommendation to you. Why did you fail to take action on that recommendation?

Dr. DAVIS. Because, as I said earlier, I felt that it was important to develop an overall departmental strategy and that there were serious problems within the whole ESRD program that needed to be looked at, not just transplantation alone. I felt that we deserved to sit down as a department and look at a number of these areas and develop a cohesive strategy of which transplantation would be one part of it. So I wished to delay that particular component and integrate the findings into the overall interdepartmental group.

That was done and the report was completed in April. As an outgrowth of that report, both Dr. Brandt and I have begun to implement some of the ideas from the interdepartmental group.

Mr. GORE. Well, in the meantime, what happens to the CDC demonstration projects? They are put on the shelf?

Dr. DAVIS. The CDC demonstration project was completed, as Dr. Brandt said.

Mr. GORE. No, no, that is the pilot study.

Dr. DAVIS. That is right.

Mr. GORE. The second phase was the one that was going to be the five demonstration projects, which would not only increase donor availability but also save the taxpayers money, and the estimates are that it would have saved a great deal of the taxpayers' money.

You got a recommendation in July of 1981 that you go forward with that. As I understand your testimony here, you are saying that you have put it on the back burner to wait until some other work on the kidney program gets done——

Dr. DAVIS. As a total integrated strategy.

Mr. GORE [continuing]. And you may or may not include that in with other recommendations.

Dr. DAVIS. No, sir. What I said was that we wanted to develop a total integrated strategy for all of the activities as they relate to the end-stage renal disease program. That is why we had the interdepartmental task force. The outgrowth of that task force was the report in April 1982 and, if you will recall, the September 16, 1982, Federal Register notice which indicated that we had an interest as part of our research program activities in studying kidney transplantation as an alternative to lifetime dialysis. The notice stated that we wanted to look at two things: first of all, an analysis of the difference in the outcomes and the related factors in relationship to kidney transplants by looking at demography and age and geography and all of those things; and, secondly, as another factor, we wanted to study the development and testing of systems that included incentives to promote the availability of kidneys.

Mr. GORE. Yes.

Dr. DAVIS. So I think it does show that we do have an interest in continuing innovation in this area.

Mr. GORE. Dr. Davis, let me try to ask the question in a little different way. I am getting a little confused.

The recommendation for five regional demonstration projects, what is the status of that recommendation?

Dr. DAVIS. That recommendation was made to the previous administration, and that recommendation was not approved by HCFA. I cannot answer the reason why.

Mr. GORE. No, no. Excuse me. That recommendation was in this administration. It was originally in the previous administration in March of 1979, a proposal for an expanded kidney procurement/retrieval effort. But then in this administration, your Office of Special Programs, before you abolished it, or before it was abolished—I don't know who was responsible for that——

Dr. DAVIS. I integrated the individuals into other parts of the agency.

Mr. GORE. All right. Before they were integrated elsewhere, in July of 1981, that Office of Special Programs recommended to you that you go forward with the five demonstration projects to further demonstrate the donor availability success as shown in the pilot study and, at the same time, save the taxpayer's money.

What I am getting at is, what is the status of that recommendation which was made to you? Have you rejected it or accepted it or what?

Dr. DAVIS. I held it in abeyance until we completed our work on the overall departmental strategy.

Mr. GORE. Has that been completed?

Dr. DAVIS. The work on that——

Mr. GORE. Has the overall strategy been completed?

Dr. DAVIS. Yes, sir, it has, and we are now——

Mr. GORE. OK, well, now, has that recommendation remained in abeyance?

Dr. DAVIS. Yes, it has remained in abeyance because I think that there have been a number of new activities that have occurred in the meantime, and I wish to update our knowledge as to whether or not that same type of program and the $3 million that would have been spent were appropriate in light of the new techniques and knowledge that we have, or whether there are more effective ways of public education.

Mr. GORE. How long do you anticipate it will remain in abeyance?

Dr. DAVIS. We expect to have the results from our new studies. As I mentioned earlier, the Brandeis study has been looking at the whole area of organ procurement, and I expect that its results will be in within the next year.

Mr. GORE. Yes. He is testifying to us on a later panel.

Dr. DAVIS. Yes.

Mr. GORE. You also got a recommendation for the development of a national transplant registry. Several other witnesses in our hearings 2 weeks ago made a similar recommendation. Is that recommendation also in abeyance?

Dr. DAVIS. The task force group, I believe, did consider that particular activity and determined that HCFA should take a lead responsibility in terms of acquiring the data that would be available for all component parts of the end-stage renal disease program.

Mr. GORE. Are you going to——

Dr. DAVIS. We are trying now to determine what is the appropriate amount of money that we would be spending and how we would develop the data collection component for the end-stage renal disease program.

Mr. GORE. So you do intend to establish a national transplant registry?

Dr. DAVIS. No, sir. I am indicating that the broader strategy was to collect data on all of the component parts of the end-stage renal disease program.

Mr. GORE. Well, what about the recommendation that you develop a national transplant registry? I don't mean to be too persistent on this, but are you going to accept or reject that recommendation?

Dr. DAVIS. I cannot speak to that at this point in time because that recommendation came out of an initial paper 2 years ago, and we will have to take those things into consideration again.

As I indicated, it was part of the overall interdepartmental strategy when we looked at it, but I do not recall a specific recommendation that related to that.

Dr. GORE. Well, I do not mean to sound unkind, but the speed with which you appear to be evaluating the recommendations on how to enhance donor awareness seems to be equivalent to the speed with which you are reevaluating the alleged experimental nature of the transplant procedure.

In both cases, it is taking an unacceptably long amount of time, and I just think that we could do a lot better.

Have you determined how you will allocate costs of organ procurement under prospective payment procedures?

Dr. DAVIS. Well, as you know, the prospective payment procedure does set a specific rate according to the DRG, and there will be a DRG for transplantation, but it will be specifically on the kidney transplantation. It is DRG-302.

In relationship to how we will pay for the organ procurement, no. We have that under study at this point in time, because we do not want to develop a system that would penalize or cause unnecessary deterrents to the organ procurement program. So I have to make some decisions in the near future on that.

Mr. GORE. Did you stimulate this letter that was referred to in the testimony 2 weeks ago alerting hospitals to potential problems with their insurance coverage if organs other than kidneys were removed from the same donor? Do you know the letter that I am referring to? It was mentioned several times in the testimony 2 weeks ago.

Dr. DAVIS. I believe the letter you are referring to is something that the intermediary sent out as a point of clarification.

Mr. GORE. Aetna sent it out, and Aetna said that your agency told them to do it.

Dr. DAVIS. Well, since we only pay for kidney transplants, then, yes, I think it would be appropriate to say that the clarification probably did come from our statement. Since we cannot, at this point in time, pay for the non-kidney organ, transplantations because they are still experimental, then that would be an appropriate assumption to make.

Mr. GORE. So what is a doctor supposed to do if he has a donor and the parents say, "Look, we want to save as many lives as we can as the result of this tragedy." In our moment of tragedy, we recognize the opportunities, as Dr. Koop stated earlier—and this is a key to the problem, families making this sort of decision.

Let's say the family makes that decision and they want to donate a liver as well as the kidneys, and yet the doctor removing the organs is advised that he may lose his insurance coverage if he removes something in addition to the kidney. That is what the implication of the letter from Aetna was. Did you intend that?

Dr. DAVIS. No. Let me clarify what the intent is. The intent is that the organ procurement costs will pay the full cost for the kidney removal and/or a corneal removal. In effect, what that means is that the cost for removal of an additional organ such as the liver, heart, lung, or pancreas would be a marginal cost, and those costs would be assumed elsewhere.

But, in effect, as you can see from chart 4, a large number of organ procurement centers do get full-cost reimbursement for the kidneys. I think you will find that a large amount of the cost for that particular agency is borne under the medicare program with respect to the kidney transplant costs.

Mr. GORE. Congressman Skeen?

Mr. SKEEN. I have one last question.

Dr. Brandt, what is the status now on cyclosporin as far as an approval? It has not had FDA approval?

Dr. BRANDT. That is correct; it does not have FDA approval. There are still some technical aspects of it with its manufacture and that sort of thing that are being reviewed by the FDA. It is always hard to preclude, but a decision will be made soon.

Mr. SKEEN. At what point, then, do you decide whether or not it is a drug for which you can make reimbursement?

Dr. BRANDT. As soon as FDA approves it, it will——

Mr. SKEEN. Thank you, Mr. Chairman.

Mr. GORE. Dr. Koop, you indicated that President and Mrs. Reagan have requested your assistance in helping families and children who need liver transplants. Can you share with us the number of families with whom you have interceded?

Dr. KOOP. I suspect probably five. My role in that has been to counsel the family, in some instances; to talk to organ procurement people in the same city; to talk to the surgeon, giving him some encouragement and some advice on where to go.

While I am saying that, sir, I would like to make one thing clear. You and we are on the same side. The only thing we differ on is speed.

Mr. GORE. Thank you.

Dr. KOOP. I think, if you look at what we have done, it is not quite as bad as it has been painted to be. It was the Public Health Service that invited the Children's Liver Foundation and Dr. Starzl here to start talking about this.

Out of that came the conference Dr. Brandt referred to, where it was decided with international experts we did not have the ability to say that this is not experimental. Then the consensus conference was set up.

When you consider the expertise and the capacity of the people coming to this consensus conference, to set it up in a year is not a long time. But then, as we saw what might happen from the consensus conference, we stepped in through my office and organized this organ procurement workshop.

We get as frustrated with slowness as you do, but I would just like you to know that our intention is right, our heart is in the right place, and we will speed it up as fast as we can.

Mr. GORE. Well, I appreciate that statement, Dr. Koop, and I hope you understand the frustration that we feel here on this subcommittee, because we have had testimony from mothers and fathers with children in the room who will live or die depending upon whether they get the procedures in question.

In all too many cases, they have been told that they cannot save the lives of their children unless they can get the money to pay for the operation.

Then we have had testimony from doctors who have described the dramatic successes now occurring with this procedure.

And then to encounter, I guess, any slowness on the part of the Federal bureaucracy is really very frustrating, but I appreciate your statement very much.

Mr. **Skeen**. Will the chairman yield?

Mr. **Gore**. Yes, I will be glad to yield.

Mr. **Skeen**. I thank the chairman.

I think, too, that it points out what has happened to us, and thank goodness it does progress in this manner, that the technology progresses more rapidly than the regulatory groups and the legislative bodies do, and we are glad for that rapid progress.

If we can find some way, together, that we can speed up the administrative process, this subcommittee will do whatever it can.

Mr. **Gore**. Incidentally, Dr. Beary, CHAMPUS did pay for liver transplants in the past, didn't they?

Dr. **Beary**. If they did that was probably in the pre-1975 era when the CHAMPUS administration was changed. Possibly that would explain the situation.

Mr. **Gore**. Yes. CHAMPUS used to pay for them, and I believe it was in that period, when the results were not nearly as good as they are now.

Mr. **Volkmer**. Mr. Chairman?

Mr. **Gore**. Yes, Mr. Volkmer?

Mr. **Volkmer**. I would just like to ask a general question. Maybe it has been covered before. But can we envision that in the future we will have a registry for transplant organs, an availability information type system?

Dr. **Brandt**. At the present time, sir, there is a national system for kidneys. It is run by the Southeastern Organ Procurement Foundation as a private sector function. I am unaware at the present time of any other system.

However, at the conference to be held in June, certainly that will be one of the issues that will be brought up.

We also have the North American Transplant Coordinators Organization, which has a 24-hour alert communications system used by medical professionals concerned with transplantation. In the 6-month period from September 1982 to March 1983, they found matched recipients and donors for 28 hearts, 44 livers, and one heart and lung.

So there are two systems operational right at the moment. Now, whether or not they should be both private sector operations as they are——clearly, any deficiencies will be explored, I am sure, at the Conference on Organ Procurement.

Mr. **Volkmer**. These are private foundations at the present time?

Dr. **Brandt**. Yes, sir, that is correct.

Mr. **Volkmer**. Can you tell me how they are funded?

Dr. **Brandt**. I do not know, but I will find out and supply that information to you for the record.

Mr. **Volkmer**. I would like to know that.

[Material to be provided follows:]

The cost of registries that cover kidneys, such as the Southeastern Organ Procurement Foundation, are considered to be kidney acquisition costs and are funded under Medicare, Part A. Registries for extra-renal organs which are not reimbursed by Medicare are funded primarily through patient billing. An example of this would be the registry of the North American Transplant Coordinators Organization.

Dr. **Koop**. It also should be said, sir, there is a whole new breed of health professional arising on the scene. Instead of just being organ procurement people, these are organ donation people.

For example, two hospitals here in Washington jointly employ a young physician whose job it is to talk to the families of youngsters who are about to die, to compassionately get across the things I have been trying to say this morning. Then she begins to inquire, in an ever-enlarging circle around Washington, where there might be a suitable recipient.

So you have people looking for organs and people trying to give them away. I think that after we get all of these people together at the Surgeon General's conference in June, we could have a much more efficient national or regional program.

Mr. **Volkmer**. Thank you.

Mr. **Gore**. Dr. Koop, I wish to congratulate you on your June 7, 8, and 9 Conference on Organ Procurement, and the subcommittee staff will be taking part in that and has already been in contact with you and your staff, and I hope that we can work together to develop a national strategy for greatly increasing the awareness of the need for organ donation.

We are indeed on the same side in that effort, and it really needs to be done. I hope that out of that may come some stimulus to go back and look again at this CDC demonstration project proposal. We should not just automatically reject things because they came out of another administration. I am not saying that was done in this case, but the studies supporting this proposal are so impressive.

We look forward to working with you on that. I would like to thank all of our witnesses on this first panel for appearing here today. Thank you very much.

We have an addition to the witness list. Before Dr. Banta comes forward, Senator Dale Bumpers of Arkansas has asked to join in this effort, and we know of his long efforts in this field, and we would be privileged to hear from him at this time.

Senator Bumpers, we are mighty pleased to have you here today. Thank you for your special interest in this field. Please proceed.

STATEMENT OF HON. DALE BUMPERS, A U.S. SENATOR FROM THE STATE OF ARKANSAS

Senator **Bumpers**. Mr. Chairman, first of all, let me thank you for two things: No. 1, your untiring devotion to the cause for which you are holding these hearings; and, No. 2, for allowing me to come in.

I will be very brief. I do not have a prepared statement. The reason I requested permission to come here is that I share your intense feeling about the necessity of doing something. We know what we want to accomplish, but nobody is certain just yet how to go about it.

But I would simply like to say that one of the reasons I am so concerned is that my interest in this issue was piqued when I was Governor of my State, because the medical center in Arkansas was, I believe, one of the first medical centers in the country to perform a kidney transplant. We have had an ongoing program there that has been extremely good.

I do not know which ones are the best now. I know that the University of Alabama has a very good program. As you know, the kidney transplant program is perhaps the oldest, and they have the best regional setup right now for matching donors and donees.

It certainly would be good for all of us to talk to these people in depth about how they have gone about it and avoid some of the mistakes that perhaps they have made along the way.

I do not want to bore the committee with duplicating statistics that I know you have heard, but I might say one other thing. There is another very good reason, and that is that it's tragic that people are so desperate that they are calling on us as Members of Congress to help them.

Yesterday, we got a call in our office from the Montefiore Medical Center in New York. There is a 60-year-old retired Air Force colonel there who is awaiting a lung transplant. My guess is that most people, and maybe some in the medical profession, do not know that lung transplants can be done, because this surgery is in its embryonic stage. But Colonel Bell is suffering from a disease known as fibrosing alveolitis. Finding a donor for him is getting to a very desperate and critical point. I issue an appeal for help with this search for a donor.

Some might not be aware of the fact that the Montefiore Medical Center in New York does these transplants. There have only been, I think, 10 or 11 lung transplants done, and there has only been one since the development of cyclosporin A. While this surgery is still in its experimental stage, this drug does offer considerable promise in the field.

The one person on whom a lung transplant was performed since this new drug was developed was a Vietnam war veteran. He had paraquat lung damage and unfortunately did not survive. Even though he was the one who has received the new drug, his body was so damaged the surgery could not be successful. In the case of Colonel Bell, all of his other organs are healthy, and he would have a good chance of responding well to the surgery if a donor could be found in the next 2 weeks.

The other thing I want to point out is that we have a bank similar to the kind some of us have been thinking about in this field. This is a bank set up nationwide for missing children. You have been here since that was developed. We all voted for the funding of that.

It is my understanding, for example, that a kidney is good for 72 hours, a liver is good for about 12 hours, heart and lungs are good for about 4 or 5 hours. If you just look at those times, you might conclude that perhaps the only sensible thing to do is a regional bank, simply because of the time. If somebody dies in San Francisco, you will not have time to excise the organ if it is a heart, for example, and fly it to Miami.

But it seems to me that this would not be a detraction from a national computer bank system. In this kind of technological age, it seems to me foolish that we don't have a national computer system to match donors and donees almost immediately.

The other big problem—and I know you have talked about this today—is that perhaps our police have not been trained well to look for the donor card on the bodies of victims of automobile accidents.

In Arkansas, as well as in about two-thirds of the States of this country, we have a notice of willingness to be a donor on our driver's licenses. This committee would have better information on that than I do. But I think the information on the backs of driver's licenses could be improved somewhat. We are not going to impose on the States some kind of standard for their driver's licenses, I assume, but if that were national, if there were some kind of a uniform donor system notice on the backs of driver's licenses, it would not take 24 hours to tell every policeman, every State trooper in the country, where to look immediately for this kind of information.

I have some statistics here which, incidentally, were really interesting to me. In my State, we have 50 people waiting for kidney transplants, and about 30 people on a cornea transplant list. Last year in the Nation, there were 4,800 kidney transplants, but there are 5,000 people now on dialysis, waiting for a kidney.

We are doing about 100 heart transplants a year. Here is the real raison d'etre for this hearing: 20,000 people are going to die this year of head injuries or some other trauma that would leave their organs extremely acceptable; and yet only a small percentage of those people's organs will be used.

Of all the people who die in hospitals every year, it is estimated that only 2 percent of them would be suitable donors, and of that number, less than one-fifth are being used.

So, if you look at those statistics, it is quite obvious that if we really made a monumental effort as we should, if all the people dying in hospitals were donating their organs and they were being used, we would probably have a donor for just about everybody that is on the waiting list.

Mr. Chairman, that just about sums up everything I wanted to say on this. I admit it probably does not add a lot to the edification of the committee, but I wanted to be on record expressing my very strong support for what you are trying to do here.

Mr. **Gore**. It adds a great deal, and your active help on this issue will add a great deal more, too, and we will work together on this.

Congressman Skeen has had some ideas on the nationwide computer bank similar to the ones you have just expressed.

Do you have any questions?

Mr. **Skeen**. Thank you, Senator. I think you have contributed a great deal. We appreciate your being here today. It is this kind of interest that I think emphasizes what we are trying to do here, and that is to provide for a kind of public awareness of just what we are losing.

When you give us the numbers that you have right now, that with all the people on dialysis, they would have a kidney within this year if there were a suitable donor program initiated or some informational system in effect that could match up those people with their kidneys, and the donors were willing. I think that you have made a very significant contribution to it, and I thank you.

Senator BUMPERS. Congressman Skeen, if I could just say one other thing, I started out by pointing out that the monumental proportions of the tragedy are best illustrated by the fact that so many people call me, perhaps call you, desperate for national publicity to try to find a donor, as in the case of Colonel Bell, whom I have just described.

It is very difficult for me to say to Colonel Bell, yes, I will do my very best to help you. This is not the job of politicians, though, and when I realize how many people in this country are waiting for transplants, you know, in a sense you feel uncomfortable, but you cannot ever deny anybody the right to try to find an organ.

One of the really good effects of that is—both in what I am saying about Colonel Bell and what this committee did for the Nation the other day in the liver transplant case for the child in Memphis—those are the kinds of things that have probably done more to raise the awareness level than anything else we could have done.

Mr. SKEEN. I share your concern, too, because using the media as a method, or politicians, if you will, either one, makes you sometimes wonder about the justice of this. What about the person who does not have that kind of access and that you are jumping one case over some others?

Senator BUMPERS. Exactly. We all feel a little uncomfortable with that.

Mr. SKEEN. It makes me very uncomfortable, and I am sure it does everyone else.

But I thank you, Senator, for your personal contribution.

Senator BUMPERS. Thank you, Congressman.

Mr. GORE. I might announce that at the beginning of the hearing, I talked about the two children in Memphis, Brandon Hall, who is doing much better. I said that Jerry Harrison was still awaiting a liver. We just received word that he died this morning at the LeBonner Hospital in Memphis; 6 years old, from Indianapolis, died of irreversible liver failure. He was number one on the list and awaiting a transplant at the time.

Senator, thank you very much.

Senator BUMPERS. Thank you, Congressman Gore and members of the committee, for inviting me over here.

Mr. GORE. We will talk later, too, about things that we can do together in the future on this. Thank you so much.

Senator BUMPERS. Thank you.

Mr. GORE. Our next witness is Dr. H. David Banta, Assistant Director of the Health and Life Sciences Division with the Office of Technology Assessment here in Washington.

Dr. Banta, we are delighted to have you here. We are cognizant of the fine work you have done in this area, and we are most eager to hear your testimony.

Please proceed.

STATEMENT OF H. DAVID BANTA, M.D., ASSISTANT DIRECTOR FOR HEALTH AND LIFE SCIENCES, OFFICE OF TECHNOLOGY ASSESSMENT

Dr. BANTA. Thank you very much, Mr. Chairman and Mr. Skeen.

I am pleased to appear before you today to discuss issues of human organ transplantation and medical technology assessment.

OTA has conducted a few specific studies of organ transplantation and artificial organs; for example, end-stage renal disease and the artificial heart. Although my remarks will draw upon that work, they will be most heavily based on OTA's extensive work on the importance and status of medical technology assessment and on techniques and systems for conducting assessments.

Organ transplantation, as you have heard, is clearly a dramatic area of medical science and technology. Advances in human organ transplantation are proceeding at an often rapid but sometimes frustratingly slow pace. Many applications are still considered experimental, as you very well know by this time; for example, by third party payers such as medicare and private insurance companies.

The testimony today from the representatives of HHS has covered the status of each transplant with regard to payment, and those statements are accurate, so I will not go into that any further at this time.

The question of experimental status is a difficult one but most likely needs to be reexamined for the various forms of transplantation due to recent advances in biomedical science, as you have also heard.

Now let me make a few comments about resource allocation. Resource allocation is, in essence, in our view, a political activity and responsibility; yet it can be informed by relevant information derived from analysis and assessment.

Organ transplantation is an area where the allocation of scarce resources demands both quantitative and qualitative data, and where social and political factors will always play by far the largest determining role.

Today we are most concerned with the allocation of resources within the area of health and health care. Even so, there is an entire series of possible ways to spend money. Few areas of medical technology point out so dramatically the tough nature of the choices to be made in allocating resources as does organ transplantation.

Consider, for example, basic research; evaluation of technology's benefits, risks, and costs; development and funding of delivery and distribution systems; health services research to improve those systems; disease prevention, screening, health promotion, and so forth; and many other possibilities.

Like it or not, when we choose to spend a certain amount of funds on any particular one of these categories, we are denying it to others.

Medical technology assessment, whether of health benefits and risks or of costs or of social implications, can provide decisionmakers with more information on which to make their decisions. It can help in showing what is known. It can point out uncertainties and assumptions. And it can sometimes help draw the dividing line between what can be decided on the basis of research evidence and what must be decided in the social or political arena.

The Federal Government has two important roles in medical technology assessment, in my view. One is the broad function of protecting the public health and promoting the general welfare. Funding of biomedical research and general medical technology assessment activities fall under this responsibility.

The Federal Government also has a specific role in the medicare program to assure that all reasonable and necessary care—and that is the language of the statute—is available to beneficiaries.

In both cases, the central task of technology assessment is to assure two goals: first, that technologies provided to the public be known to be efficacious and safe; and, two, that all technologies known to be efficacious and safe are broadly available.

In OTA's September 1982 report, "Strategies for Medical Technology Assessment," we found the Federal Government's activities to be inadequate in a number of areas. Only drugs and devices, as was stated this morning, are examined in a systematic way as part of the activities of the Food and Drug Administration.

Mr. GORE. Excuse me. You are on page 11 at the bottom now?

Dr. BANTA. Yes, sir.

Mr. GORE. Thank you. Go ahead.

Dr. BANTA. The Congress addressed these problems in 1978 in passing legislation to establish the National Center for Health Care Technology, NCHCT, but administration budget cuts led to NCHCT's dissolution in 1981.

Although a remnant of NCHCT, the Office of Health Technology Assessment, OHTA, which you heard referred to this morning, still handles medicare coverage decisions for the Public Health Service, many problems remain unaddressed. There is in fact no systematic identification of medical and surgical procedures needing assessment. Investments in testing, such as clinical trials, are small relative to the needs for information. Synthesis and summary activities are generally undeveloped, and dissemination of results has actually been cut back in the past few years.

The Government's activities concerning the medicare program illustrate some of these problems. Medicare has interpreted its mandate to provide medically necessary services as requiring it to ask three questions before a new technology is covered:

First, is the procedure safe? Second, is the procedure effective? Third, does the procedure have the acceptance of the medical community?

I might note that the term "reasonable and necessary" has never been defined in regulations.

Until late 1979, the procedure for making these coverage determinations was highly informal. OTA criticized this process in its 1978 report on computed tomography—CT—scanning. In 1978, Congress addressed the problem in mandating NCHCT review of medicare coverage decisions as part of that agency's responsibilities.

Since 1981, when NCHCT disappeared, the OHTA has operated at a lower level of effort than the NCHCT did. This is clearly illustrated by the fact that the issue of liver transplant, which was found experimental because of lack of data in 1980, has not been reexamined, despite the accumulating evidence, and you have heard plenty of mention of that this morning.

While I strongly support the attempts to assure that new procedures are efficacious, I also believe that it is very important that decisions not to cover new technology must be reexamined at frequent intervals in rapidly moving fields of medicine, and especially when the procedures may be lifesaving.

Perhaps the most distressing case is that of heart transplant. The NCHCT recommended that it be covered at selected centers in February 1980. It is still not covered. The rationale was that heart transplant raises many ethical and economic questions, as well as efficacy and safety questions that are being addressed in the Battelle study.

The previous Secretary of HHS, Patricia Harris, decided that heart transplants should not be covered. However, I should note that HCFA does not have the authority to base payment decisions on such broader considerations as cost and ethical considerations. Under HCFA guidelines, I believe heart transplants should be provided already.

I am sympathetic with the administration's concerns about transplants. However, technology must be addressed in a consistent manner. If HCFA lacks the authority to limit transplants to certain centers, it could request that authority. If HCFA wishes the authority to base decisions on economic and social criteria, it can request Congress to give it that authority. And, by all means, HCFA should define "reasonable and necessary" by regulation.

One is left with the impression, in the case of heart transplant, at least, that HCFA is delaying payment for cost containment reasons. If this is a true perception, this is a serious perversion of the process of technology assessment and its place in policymaking.

In summary, I see many problems in the Federal Government's activities in medical technology assessment, both with regard to the general society and with regard to the medicare program.

Thank you, Mr. Chairman. I did summarize my testimony, and I would appreciate it if the entire text were put into the record.

I would be happy to address any questions.

Mr. GORE. Without objection, it will be.

[The prepared statement of Dr. Banta follows:]

STATEMENT OF

H. DAVID BANTA, M.D.
ASSISTANT DIRECTOR
FOR HEALTH AND LIFE SCIENCES
OFFICE OF TECHNOLOGY ASSESSMENT
CONGRESS OF THE UNITED STATES

Mr. Chairman and Members of the Subcommittee:

I am Dr. David Banta, the Assistant Director for Health and Life Sciences, Office of Technology Assessment. I am pleased to appear before you today to discuss issues of human organ transplantation and medical technology assessment.

The Office of Technology Assessment (OTA) has conducted a few specific studies of organ transplantation and artificial organs (e.g., end-stage renal disease, the artificial heart). Although my remarks will draw upon that work, they will be most heavily based on OTA's extensive work on the importance and status of medical technology assessment and on techniques and systems for conducting assessments.

Because of this background, I will take a broad perspective in my comments. After presenting some brief material on human organ transplantation and on the types of questions or issues raised by transplantation, I shall discuss resource allocation and then cover the role and the potential contribution of medical technology assessment.

ORGAN TRANSPLANTATION

Organ transplantation is clearly a dramatic area of medical science and technology. Advances in human organ transplantation are proceeding at an often rapid but sometimes frustratingly slow pace. Many applications are still considered experimental, e.g., by third party payers such as Medicare and private health insurance companies. Heart transplantation, as you know, is not presently covered by Medicare, pending the results of a major evaluation of its efficacy and safety. Pancreas transplantation is not covered, although it is presently under review by the Public Health Service. Liver transplantation is also not covered based on a 1980 assessment by the Public Health Service that found the procedure to be experimental. The issue of whether liver transplants are to be considered experimental and thus not paid for has been reopened. Liver transplants will be the subject of a National Institutes of Health Consensus Development Conference in June. The Public Health Service will reassess liver transplantation following that Conference. Cornea transplants are becoming more common and the procedure is covered by Medicare on a routine basis. And of course, kidney transplants have long been considered an established treatment, and a special program under Medicare covers them.

The question of "experimental" status is a difficult one, but most likely needs to be re-examined for the various forms of transplantation, due to recent advances in biomedical science. For example, it appears that improved success rates are occurring because of Cyclosporin A, improvements in pretransplant blood transfusion matching and techniques, and increases in surgeons' experience. This does not necessarily mean that all transplantation has moved beyond experimental status, nor does it eliminate the need to consider a large set of questions that go beyond clinical risks and benefits when making decisions about transplantation.

ISSUES RAISED BY TRANSPLANTATION

Whatever their status is, and whatever the pace of advance is, however, each form of organ transplantation raises questions that need to be examined. Some questions are personal ones, to be faced by individuals. Others are for society and its institutions. Many must be considered by the Federal government, and thus are of special interest to these hearings. A sample of the questions raised follows.

1. **Research and Development Questions.** Are we focusing on the most appropriate research areas? Are funding levels adequate? What is the balance between basic research, applied research, and technology development for any particular medical technology? Is this the best use of scarce research dollars?

2. **Efficacy and Safety Questions.** What types of evaluation of current and potential effects have been done or need to be conducted? What are the medical technology's impacts on health (clinical benefit and risk) both in the short term (e.g., successful transplant rates, operative mortality, complications, graft rejection) and in the longer term (e.g., long term survival, quality of life enhancements over time)? Who will ask the assessment questions; who will attempt to answer them; and who will act based on the answers? Are data adequate?

3. **Adoption, Financing, and Use Questions.** Is the rate of adoption (initial entry of the technology into use) and then use appropriate? Are the populations most likely to benefit from the technology receiving its benefits, or is access skewed? Who will pay for the use of the technology? Are delivery systems inadequately or inefficiently organized? Donor identification and organ distribution are crucial issues here.

4. **Regulatory Questions.** What regulatory oversight is applicable to the transplantation technologies? For example, what is the role of the Food and Drug Administration? What other Federal or State programs apply? What are or will be the effects of such regulation?

5. **Ethical, Legal, and Other Social Questions.** Organ transplantation raises many sensitive issues of ethics, the law, psychology, religion, resource allocation, and so on. What social questions need to be asked in regard to the technology? Can they be raised in advance of the technology's diffusion? Can assessment provide helpful information? Who is responsible for making decisions relative to an organ transplantation technology's development, regulation, or use? And can they make such decisions taking into account the potential ethical and other social implications of the technology? Equity is a particularly important question in this area.

6. **Economic and Cost Issues.** Economic questions bring together many points raised above: Is a particular form of organ transplantation a "cost-effective" way to expend resources? Are financing schemes and delivery systems efficient (and equitable)? What are the costs implications for society of transplantation, and what are the alternate possibilities for use of such funds? Will economic decisions be made openly and explicitly or will they be made implicitly, without public scrutiny?

Such a list of questions appears formidable, even though it represents only a sample of the questions raised by any medical technology. Nevertheless, they must be asked. Organ transplantation is too important for its development and use to proceed without full knowledge of goals and possible impacts on individuals and on society.

In the list above, many of the issues directly of concern to the Federal government are obvious: funds and priorities for basic and applied research and technology development; dissemination and development of data about organ transplantation and its benefits, risks, and costs; financing of treatment; helping to assure access and equity; and regulation.

RESOURCE ALLOCATION

Resource allocation is in essence a political activity and responsibility, yet it can be informed by relevant information derived from analysis. Organ transplantation is an area where the allocation of scarce resources demands both quantitative and qualitative data and where social and political factors will always play by far the largest determining role.

One logical starting point that is often ignored or assumed away is the split between the amount of resources to be spent on health and on medical care as opposed to that allocated to all other sectors of society.[1] In the past, this choice has often been made in effect by ignoring it. This is changing, however, as society begins asking how much health care it can afford and who shall pay for it.

Today, however, we are more directly concerned with the allocation of resources within the area of health and health care. Even so, there is an entire series of possible ways to spend money. Few areas of medical technology point out so dramatically the tough nature of the choices to be made in allocating resources as does organ transplantation.

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[1] Even this basic choice is not at all clear. For example, the effects of environmental quality, urban security, housing, and so on may be quite dramatic in terms of health.

Consider the following list of ways to spend funds on organ transplantation and its alternatives for the related diseases. Funds must be or could be distributed among:

- Basic research;
- Applied research and technology development;
- Evaluation of technologies' benefits, risks, costs;
- Development and funding of delivery and distribution systems;
- Health services research to improve delivery systems and financing of treatment;
- Development and operation of communications/data handling systems and creating and disseminating data on the technologies, delivery systems, individuals in need, and potential donors;
- Disease prevention (e.g., screening, health promotion);
- Treatment of disease through organ transplantation;
- Treatment of disease through artificial organs or through other alternatives to transplantation;
- Efforts to increase public understanding of transplantation and organ donation; and
- Many more possible ways to spend funds.

Like it or not, when we choose to spend a certain amount of funds on any particular one of these categories, we are denying it to others - perhaps not directly, perhaps not explicitly. When we choose among these possibilities, we are making judgments about their relative values as "investments" of our scarce dollars, even though these judgments may be implicit or hidden. Specific relative spending patterns reflect judgments on the value of "health," on the value of extending life, on the value of enhancing quality of life, on the value of reducing expenditures (of making cost-beneficial decisions), and on the value of our image (of ourselves as individuals or as members of a human society), and many others (such as the value of being a research oriented people).

The critical problem arises when decisions that reflect a high value placed on positive economic outcomes are different from those that place a high value on other outcomes (equity, quality of life, humaneness). The decisions will not always be at odds. Investment in basic research is considered by many people to be a sound financial investment. But they will differ in many or most cases. The result is that we can not do all the things that we would like to do as members of a caring society.

This split between economic goals and health or human goals becomes especially acute in a field such as organ transplantation because transplantation is a prime example of what Dr. Lewis Thomas has called "halfway technologies." Halfway technologies are not cures, they do not eliminate the cause of disease. He does not term them "high technology" because they are in some important senses crude attempts to make up for the disease or condition. And, like most halfway technologies, organ transplants are expensive and raise great issues of resource allocation and moral and social dilemmas.

This clash between resources and medical and social goals is one major reason why resource allocation, especially in the area of organ transplantation, is and needs to be in large part a social responsibility. As I will briefly mention below, choices can be helped by formal analysis and data, but - the fact will always remain - analysis of costs and benefits will not tell us how to spend our resources. No cost-effectiveness or cost-benefit calculus can usurp the position of social and political decision makers.

MEDICAL TECHNOLOGY ASSESSMENT AND ORGAN TRANSPLANTATION

Medical technology assessment - whether of health benefits and risks, or of costs, or of social implications - can at the most provide decision makers with more information on which to make their decisions. It can help in showing what is known; it can point out uncertainties and assumptions; and it can sometimes help draw the dividing line between what can be decided on the basis of research evidence and what must be decided in the social or political arena.

In order to make the best decisions possible, society's decision makers must have the best information that is available or can be developed. Medical technology assessment can be of particular help in providing the following types of information. Some will be relatively direct and quantitative; other types will be less definitive and more qualitative.

- Data on a transplant technology's efficacy (its clinical benefits) in terms of health outcomes (mortality reduction, quality of life changes, etc.);
- Data on both short term and long term risks of the technology;
- Some measure of the costs of applying the technology, both relative to alternatives to transplantation and in terms of the potential aggregate cost to society and the specific costs to individuals;

- Information on the structure and operation of the systems for delivering the transplant technology and the systems for gathering and preparing organs;
- Information on disease prevention and health promotion as alternatives to treatment (through both transplantation and other forms of treatment) - especially information on benefits, risks, and costs relative to treatment;
- Primarily qualitative information on potential social and ethical implications of transplantation or lack of transplantation (including lack of financing or access);
- Estimates of fruitful areas of basic research and applied research and technology development in which to invest funds; and
- Ideally, some characterization or practical estimates of the near term future of disease patterns, population changes, technological advances, and social institutions changes.

These types of information may help to make decisions more rational. They will rarely if ever point to a particular decision (other than a clinical one on occasion). Some of the needed information exists, but much more is needed.

We should face our ignorance. Decisions related to transplants are tricky and there are many gaps in our knowledge. At the same time, developing and disseminating information is not an inexpensive task. We can not develop all the possible information about every type of transplant technology. Compromises and judgments about the most helpful data will have to be made.

EXECUTIVE BRANCH ACTIVITIES IN MEDICAL TECHNOLOGY ASSESSMENT

The Federal government has two important roles in medical technology assessment. One is the broad function of protecting the public health and promoting the general welfare. Funding of biomedical research and general medical technology assessment activities fall under this responsibility. The Federal government also has a specific role in the Medicare program to assure that all reasonable and necessary care is available to beneficiaries. In both cases, the central task of technology assessment is to assure two goals: 1) that technologies provided to the public be known to be efficacious and safe; and 2) that all technologies known to be efficacious and safe are broadly available.

In examining the Federal government's activities in medical technology assessment, OTA has used a simple model of information development and flow:

- Identification - Monitoring technologies, determining which need to be studied, and deciding which to study.
- Testing - Conducting the appropriate analyses or trials.
- Synthesis - Collecting and interpreting existing information and the results of the testing stage, and, usually, making recommendations or judgments about appropriate use.
- Dissemination - Providing the synthesis of information, or any other relevant information, to the appropriate parties who use medical technologies or make decisions about their use.

In our September 1982 report, Strategies for Medical Technology Assessment, we found the Federal governments activities to be inadequate in a number of areas. Only drugs and devices are examined in a systematic way as part of the activities of the Food and Drug Administration. The Congress addressed these problems in 1978 in passing legislation to establish the National Center for Health Care Technology (NCHCT), but Administration budget cuts led to NCHCT's dissolution in 1981.

Although a remnant of NCHCT, the Office of Health Technology Assessment (OHTA), still handles Medicare coverage decisions for Public Health Service, many problems remain unaddressed. There is in fact no systematic identification of medical and surgical procedures needing assessment. Investments in testing, such as clinical trials, are small relative to the needs for information. Synthesis activities are generally underdeveloped. And dissemination of results has actually been cut back in the past few years.

But perhaps the greatest problem is the lack of a systematic approach to the general problem of medical technology assessment. Such activities as there are function with little relation to each other.

The government's activities concerning the Medicare program illustrate some of these problems. Medicare has interpreted its mandate to provide medically necessary services as requiring it to ask three questions before a new technology is covered: 1) is the procedure safe? 2) is the procedure effective? 3) does the procedure have the acceptance of the medical community? Until late 1979, the procedure for making these coverage determinations was highly informal. A small staff would review the issue, consult experts in the field with whom they were acquainted, and come to a decision. OTA criticized this process in its 1978 report on computed tomography (CT) scanning. In 1978, Congress addressed the problem in mandating NCHCT review of Medicare coverage decisions as part of that agency's responsibilities. In December 1980, the Health Care Financing Administration and the NCHCT signed a memorandum of understanding formally setting-out the process for initiating and transmitting NCHCT assessments. At the time NCHCT began operations, there was a backlog of 58 requests from HCFA for coverage advice. NCHCT developed an excellent staff and a credible process of review in its two years of functioning and caught up with the backlog.

Since 1981, the OHTA has operated at a lower level of effort. This is clearly illustrated by the fact that the issue of liver transplant, which was found experimental because of the lack of data in 1980, has not been re-examined, despite the accumulating evidence. While I strongly suppport the attempts to assure that new procedures are efficacious, I also believe that it is very important that decisions not to cover new technology must be re-examined at frequent intervals in rapidly moving fields of medicine.

Perhaps the most distressing case is that of heart transplant. The NCHCT recommended that it be covered at selected centers in February 1980. It is still not covered. The rationale is that heart transplant raises many ethical and economic questions that are being addressed in the Batelle study. However, HCFA does not have, and has not requested, the authority to base payment decisions on such broader considerations. Under HCFA guidelines, heart transplant should be provided already.

Mr. **Gore**. You make some very strong statements in your testimony. First of all, you say that the Federal Government's efforts are inadequate in a number of areas. You say that many problems remain unaddressed, that the investment in testing relative to the need for information is very small; synthesis activities are generally undeveloped; dissemination of results has been cut back.

Then you say that there just is no good way, they have not developed a good way, of assessing technology. Then you conclude with this very strong statement that one is left with the impression that HCFA is delaying payment for transplants for cost containment reasons. You state: "If this is a true perception this is a serious perversion of the process of technology assessment and its place in policymaking." That is a very, very strong statement.

In the earlier panel, we had the fellow from CHAMPUS turning down the transplant procedure for the children that need it covered by CHAMPUS on the basis of the slow progress being made—on the basis of the decisions made by HHS. HHS, when we turned to them, said that their process is, they think, a good one, and that they are just moving along as far as they can.

But here you, with the Office of Technology Assessment, have conducted an exhaustive study of exactly the procedures that are being used at HHS, and you say they are inadequate, and you are left with the impression that they are delaying payment for cost containment reasons, a serious perversion of the process of technology assessment and its place in policymaking. That is a very, very strong statement.

Let's take a closer look at the heart transplant question here. Now, this National Center for Health—what does NCHCT stand for again?

Dr. **Banta**. The National Center for Health Care Technology.

Mr. **Gore**. Now, that was established by the Congress in 1978——

Dr. **Banta**. Yes, sir.

Mr. **Gore** [continuing]. As a way to make precisely the decisions that are not being made, or that are being made so slowly, with respect to transplants. Correct?

Dr. **Banta**. That is correct, sir.

Mr. **Gore**. Liver transplant.

Dr. **Banta**. And it was set up to address both elements, both the general technology assessment function and the coverage question for medicare.

Mr. **Gore**. Now, as part of the Gramm-Latta budget resolution—that was the great big thing that contained the whole Federal Government all in one fell swoop—this Center was abolished in that legislation. Is that correct?

Dr. **Banta**. Yes, sir, but I should note that the administration put no money in their own budget for the Center. Congress could have reversed the administration's decision, but it was fundamentally the administration's decision.

Mr. **Gore**. Even before Gramm-Latta——

Dr. **Banta**. That is correct.

Mr. **Gore** [continuing]. The administration decided that they did not want this. Do you know why?

Dr. **Banta**. It is hard to say, Mr. Chairman. There have been a lot of speculations, and I guess the one that I have tended to believe myself is that David Stockman had some concerns about a Center that was established in legislation that was supported primarily by Senator Kennedy. [Laughter.]

Mr. GORE. All right.

Dr. BANTA. There are many other factors, but that at least is my own interpretation.

Mr. GORE. Now, before it was abolished, it looked at the question of heart transplants and decided that they ought to be approved by HCFA.

Dr. BANTA. Yes, sir, under specified circumstances.

Mr. GORE. In carefully specified circumstances.

Dr. BANTA. That is right.

Mr. GORE. But HCFA decided to ignore that recommendation?

Dr. BANTA. Yes, sir, the details of the situation were that medicare was paying for heart transplants at Stanford University under an interim decision. About the same time that NCHCT made its recommendation, the University of Arizona billed for a procedure, was denied by medicare, and the University of Arizona appealed to an administrative law judge, who found that medicare must pay the University of Arizona if it was going to pay Stanford.

This, I think, raised the question in the Secretary's mind as to whether the Department could limit payment to certain selected centers, and the decision was made not to pay at all rather than try to pay in certain selected centers.

Mr. GORE. I see. And you have some difficulty escaping the conclusion that they are not really assessing the technology; they are just deciding that they don't want to spend that money.

Dr. BANTA. Well, you have heard from Roger Evans at these hearings. Dr. Evans is a very good researcher, and I think the research project is very well worth doing. That is a separable question from whether heart transplants should be paid for or not, however.

A procedure was set up here, a process was followed, and HCFA did not follow out its own process in deciding whether or not to pay. That is my objection to this particular procedure.

Mr. GORE. Now, you are aware of the provisions in the Social Security Act, just signed into law, which establishes a new commission for the purpose of assessment of medical procedures and services, are you not?

Dr. BANTA. Yes, sir, very aware.

Mr. GORE. This legislation provides for OTA to appoint the commission.

Dr. BANTA. Yes, sir.

Mr. GORE. What other role do you foresee for OTA?

Dr. BANTA. Well, the way we formulate our role at the minute is that we would appoint the commission, as you say, with a process of the greatest integrity that we could devise.

After that, we would stand back and let the commission function independently, but we do have a responsibility to report to the Congress once a year on the functioning of that commission.

Mr. GORE. I see.

Dr. BANTA. I am glad you brought up the commission because I think it is a very good example of how procedures can be set up for the purpose of assuring that new beneficial technology is incorporated into the medicare program.

Mr. **Gore**. Now, can that commission perform the role that the one that was just abolished performed?

Dr. **Banta**. Yes, Mr. Chairman, it will certainly perform part of that role. Since the DRG program only covers hospital care under the legislation, though, there still is all the rest of medical practice to consider.

Medicare coverage decisions deal primarily with physicians. The new commission will take over a piece, but most of it would remain with the old remnant.

Mr. **Gore**. In your view—now, you have looked at the procedures. Dr. Davis outlined her procedure with the seven steps and all the boxes and stuff. Is that the one that you are saying is inadequate?

Dr. **Banta**. The comments about inadequacy were really addressed to a broader question, not so much the way the medicare program and the Public Health Service carry out their functions but that, in my view, at least, the Federal Government has a broader responsibility to assure that medical technology is safe and efficacious.

The Federal Government's activities in this area are really inadequate. I think the medicare program in general, since 1978, has done a pretty good job of assessing the technologies that have come before it, and the Public Health Service, with NIH, CDC, and all the other resources of the Public Health Service have done that pretty well. So, when I pick out heart transplant as an instance to criticize, I think that is an almost unique instance, and I do not know enough, frankly, about the evidence of liver transplant to say if that should be covered or not.

Mr. **Gore**. All right. I was just about to ask you about that. The evidence that has been presented to us indicates a 70- to 80-percent success rate in those centers that are doing the procedure.

Dr. **Banta**. I do have the same concern that you do, Mr. Chairman. Liver transplant was first considered by the Public Health Service 2½ years ago.

Mr. **Gore**. Yes.

Dr. **Banta**. And the people who participated in that process at NIH and NCHCT told me informally that they anticipated the question would have to be reopened soon because of the accumulating evidence.

Mr. **Gore**. Yes.

Dr. **Banta**. So, I think your putting your finger on the question of slowness is exactly the right point. It is not so much that the procedures are inadequate. The procedures are important and they generally run very well, but they run very slowly, at least in these cases of transplant.

Mr. **Gore**. Yes; well, you are familiar with the general framework of bioethics. You have to be in pursuit of your work. At what point does the slowness of the reevaluation acquire bioethical implications? If patients are dying while the decisionmaking process is dragging on, at some point it seems to me we have a bioethical imperative to make those decisions in a more expeditious fashion. Wouldn't you agree?

Dr. **Banta**. I certainly agree with that. It is a difficult area. When people are dying, they are desperate; the physicians are desperate; and there is a tendency to use things prematurely. And so I am sympathetic with the Department's desire to approach those questions carefully. But still, I stand by what I said in the case of heart transplant, that at least in that case I think the decision should have been made some time ago.

Mr. **Gore**. Now, clinical trials are expensive and difficult to perform. Yet, they are generally regarded as necessary for judgments on new therapies and procedures to be made appropriately.

Who should have the responsibility for supporting these studies? Should it be NIH or HCFA or this new assessment agency that you are appointing? Who should do that?

Dr. **Banta**. Well, I don't see one responsibility, Mr. Chairman. I think the private sector certainly supports clinical trials. The largest supporter of clinical trials in this country, aside from NIH, is probably the drug industry, because they are required to do clinical trials under the drug regulation statutes.

There are many sources of funding and support for clinical trials. But there are inadequate funds, and this kind of research, just like biomedical research, does not attract large private sector resources. I think the public wants to be assured that medical technology is safe and efficacious, and I believe the public is ready to pay out of its own funds to assure that appropriate clinical trials are done.

So, I would say not so much that it is NIH's responsibility as that the Federal Government has a broad responsibility, and Congress has some responsibility to see where that kind of program would actually be carried out.

Mr. **Gore**. All right, very good.

Without objection, I want to include in the record the entire text of your summary, "Strategies for Medical Technology Assessment," dated September 1982. I think it is the single best work that has been done on these questions, and I want to congratulate you and your colleagues at OTA for the work which went into that. I trust it will be a useful part of this hearing record as those who read it, hopefully, will be trying to figure out how we can solve these problems.

[Material to be supplied follows:]

STRATEGIES FOR MEDICAL TECHNOLOGY ASSESSMENT

SEPTEMBER 1982

Summary

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Office of Technology Assessment
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The Technology Assessment Board approves the release of this report. The views expressed in this report are not necessarily those of the Board, OTA Advisory Council, or of individual members thereof.

Foreword

This summary presents the findings of OTA's study *Strategies for Medical Technology Assessment*. OTA began the study in July 1980, at the request of the House Committee on Energy and Commerce.

The full report focuses on the flow of information that is central to an effective assessment system. It critiques the current assessment system with respect to identifying medical technologies for assessment; developing and synthesizing information about such technologies' health, economic, and social effects; and disseminating this information to health care decisionmakers. This summary presents the highlights of that critique. It also provides a list of policy options, both legislative and oversight, for Congress to improve the system.

During the course of this assessment, both the House Committee on Energy and Commerce and the Senate Committee on Labor and Human Resources requested that OTA study several specific areas in more depth. In response to these requests, OTA is publishing three other volumes: 1) a report on medical technology under proposals to increase competition in health care, 2) a report on the postmarketing surveillance of prescription drugs, and 3) a technical memorandum on MEDLARS (the National Library of Medicine's Medical Literature Analysis and Retrieval System) and health information policy. Another paper, funded as part of this assessment, concerns the potential role of Professional Standards Review Organizations in medical technology assessment.

Drafts of the final report were reviewed by the advisory panel chaired by Dr. Lester Breslow, by the Health Program Advisory Committee chaired by Dr. Sidney S. Lee, and by approximately 100 other individuals and groups representing a wide range of disciplines and perspectives. We are grateful for their many contributions. As with all OTA reports, however, the content is the responsibility of the Office and does not constitute consensus or endorsement by the advisory panel or the Technology Assessment Board.

John H. Gibbons

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*Until January 1982.
**Until September 1981.

Strategies for Medical Technology Assessment

Knowledge advances by steps, and not by leaps.

—Thomas Babbington Macaulay

NEED FOR A STRATEGY

Several reasons for assessing medical technologies have been presented in previous OTA reports, *Assessing the Efficacy and Safety of Medical Technologies* and *The Implications of Cost-Effectiveness Analysis of Medical Technology*. The main reasons are to help ensure that medical technologies are safe, efficacious, and appropriately used. Whether current policies and practices for medical technology assessment achieve these and related objectives is the subject of this report. Having studied both the methods of medical technology assessment and the dissemination of information developed by technology assessment, OTA finds that a strategy is needed to implement the assessment process to make it more effective. OTA also finds that greater attention to assessment of social and ethical values is needed for policymaking.

A *medical technology*, as used in this report, is a drug, device, or medical or surgical procedure used in medical care. (The term may also apply to the organizational and supportive systems within which medical care is delivered, but those systems are not the focus of this report.) *Medical technology assessment* is, in a narrow sense, the evaluation or testing of a technology for safety and efficacy. In a broader sense, it is a process of policy research that examines the short- and long-term consequences of individual medical technologies and thereby becomes the source of information needed by policymakers in formulating regulations and legislation, by industry in developing products, by health professionals in treating and serving patients, and by consumers in making personal health decisions. Unfortunately, that process currently has deficiencies that cause or allow confusion to exist at all decision points.

Historically, medical technology assessment has developed incrementally as responses to specific demands. Taken singly, some of these responses have been coherent (e.g., the Food and Drug Administration's (FDA's) premarketing approval process which was developed to protect the public from unsafe and inefficacious new drugs). Taken in combination, however, these various responses do not constitute a coherent system for assessing all classes of medical technologies. The present approach is characterized by multiple participants from the public and private sectors, and by uncoordinated activities. Complicating matters further is the large number of medical technologies in use, with thousands of new technologies appearing every year. The result is an overload and confusion among decisionmakers and consumers.

OTA finds that a strategy is needed to guide the selection and implementation of components that would constitute a coordinated system of medical technology assessment. The basis of the strategy should be the values and available resources in a free-market economy, coupled with the social responsibility to make available safe, effective medical care. The vehicle of the strategy should be a systematic process of information development, dissemination, and use. The target should be to address the confusion deriving from the lack of information available to decisionmakers.

Minimally, the following components of an assessment system must be considered in developing a strategy:

1. the values of individuals and of society concerning medical technologies and their use;
2. the goals and appropriate role of medical technology assessment in society;
3. the types of assessment information needed for decisionmaking;
4. the methods and technologies for developing and acquiring the information; and
5. mechanisms for disseminating and applying the information, including programs that will use the information.

A strategy for assessing medical technologies must consider not only the methods of assessment, but also the needs, demands, and resistances of potential participants in the process of assessment. Specifically, the public itself as consumers; health care professionals as users; industry as innovators, producers, and reimbursers; and the Federal Government simultaneously as purchaser and guardian must be informed and active in setting mutually compatible goals for technology assessment. Each sector has health, social, and economic values underlying its decisionmaking. Clarifying those values and realistically accommodating them will require developing not just more, but also more reliable, information about the safety, efficacy, cost effectiveness, and social and ethical implications of all classes of medical technologies. The inconsistencies and contradictions in available information are reflected in the inconsistent and competing pressures from the various sectors.

DIMENSIONS OF THE NEED AND THE PROBLEM

Most medical technologies have a therapeutic or diagnostic value for specific problems under appropriate circumstances. The difficulty is determining for whom and under what circumstances use of a technology is valid or worth the tradeoff of risks and benefits. Mammography and radical mastectomy, for example, have a place in the detection and treatment of breast cancer, but understanding exactly what that place is may take years and a certain amount of trial and error.

Government

The Federal Government's interest in developing clear policies and an effective strategy for assessing medical technology derives from its traditional role as guardian of the public's safety and of social equity and from its concerns about economic issues. As protector of the public, the Government seeks to ensure that health care is not only safe but also efficacious. As the single largest buyer of health services, the Government seeks to ensure that all citizens, especially the poor, have health care available to them; but the Government is also concerned about rising health care costs in general and specifically about those it pays for directly through programs of service or reimbursement (Medicare, for example) and through biomedical and other health research. Any policies the Government sets will affect not only the Government itself, but the public and private industry, and such policies must especially be justifiable when the public and private industry make self-interested demands.

The Public

The public is often neither fully informed about the safety and efficacy of individual technologies nor educated about the issues of cost and social values that must be considered in the adoption of a technology. The public mixes facts with beliefs, hopes, and fears and translates those into confused, contradictory, and often impossible demands.

For example, the public hears of a drug, perhaps one used in another country, and wants it immediately available to patients in the United States, especially when available therapies are ineffective. The desperation individuals feel tends to outweigh the fear of any risks that might be involved, and they demand the right to take personal responsibility for use of the drug. Perhaps assuming that if a therapy is used in a European country, it has already met rigorous assessment standards, the public perceives itself as being denied a cure for no valid reason.

Simultaneously to demanding speedy availability and personal responsibility, however, the public demands protection against all forms of unsafe medical practice and is prepared to sue for mistakes. Perhaps because of the rigor which FDA applies to approval of new drugs and because of Government safety standards applied to so many nonmedical products, the public assumes that it is likewise protected in undergoing any medical or surgical procedure recommended.

The confused demands of the public can be viewed either as irrational or as a frustrated reflection of the deficiencies that do exist in the Nation's approach to assuring the availability of safe, effective, and cost-effective medical technologies. Numerous needs and values are implied in the demands of the public and must be taken into account when planning a strategy of policies and procedures for medical technology assessment.

Health Professionals

Health professionals often find themselves in circumstances that require decisions based on inadequate information. The flaws in the information flow to physicians and other health professionals are numerous: there is not enough information available about the safety, efficacy, costs, and social values of medical technologies; much existing information is of dubious quality and is therefore unreliable; the practical significance of data is usually not interpreted for clinicians; and easy access to the appropriate information is rare.

Furthermore, medical education typically does not train physicians and other health care professionals to make decisions based on a consideration of values. They are trained to seek the most reliable technique to produce a desired physiological response. As an illustration, in the issue of saving the lives of extremely premature babies in incubators, physicians, by training, would tend to be concerned mainly with choosing the technology that would support life. Physicians would less likely know or be concerned about the implications of the survival of the deformed or retarded infant—implications for the infant itself, for the family, and for society. Thus, developing and supplying the right kind of assessment information to health care professionals is essential to a strategy for medical technology assessment.

Industry

From the point of view of the private sector, of producers of technologies, and of third-party payers, the assessment of medical technologies is both advantageous and disadvantageous. Government's involvement in the assessment process raises primarily financial issues for the private sector.

Industry, which invests money in research and development (R&D), is willing to do so if there is a potential market for the device or drug; however, excessive regulation or the wrong kind of regulation by the Government could discourage innovation if companies fear that assessment will ultimately preclude marketing their product or making a profit from it.

Private third-party payers, on the other hand, might welcome shifting the entire burden of assessment to the Federal Government. They must make decisions about reimbursement—whether to reimburse for specific procedures and if so how much—but they have little incentive to conduct their own assessments of procedures because of the expense. Assessment information tends to be widely available and not proprietary; the insurance companies cannot profit individually from conducting assessments. The failure of industry members to adequately conduct assessment activities on their own puts a heavy responsibility in the Government domain.

Nature of the Challenge

The market for medical technologies is moderated by individual consumer tastes and financial constraints. To perhaps a greater degree, it is influenced by policies that determine what kinds of research will be supported, what regulations restrict market entry, and which technologies will be reimbursable by Government or private programs.

No policy decision has isolated effects in just one sector; repercussions occur throughout the entire social and economic fabric of the Nation. A regulatory decision to require extensive, expensive assessment of a medical device in a developmental phase, but not to offer industry assistance in the assessment, for example, could lead to a decision by industry never to begin the innovation phase. An idea might never be realized which eventually could have best served the public. In fact, current policies and procedures for assessment are not adequate to fully serve the public interest. No consistent policy or system exists for assessing all classes of medical technologies, nor even for various technologies within a class.

Reimbursement decisions also influence the innovation and adoption of medical and surgical procedures. Although new procedures tend to be adopted and reimbursed without adequate assessment, in the case of truly innovative procedures, third-party payers sometimes refuse reimbursement. While encouraging new applications, slight modifications, and excessive use of existing technologies, the present reimbursement system may discourage radical innovations.

The challenge in developing a strategy for assessment is to develop a system that will serve the public interest by encouraging the development and appropriate use of needed and safe medical technologies without unnecessarily discouraging innovation and production.

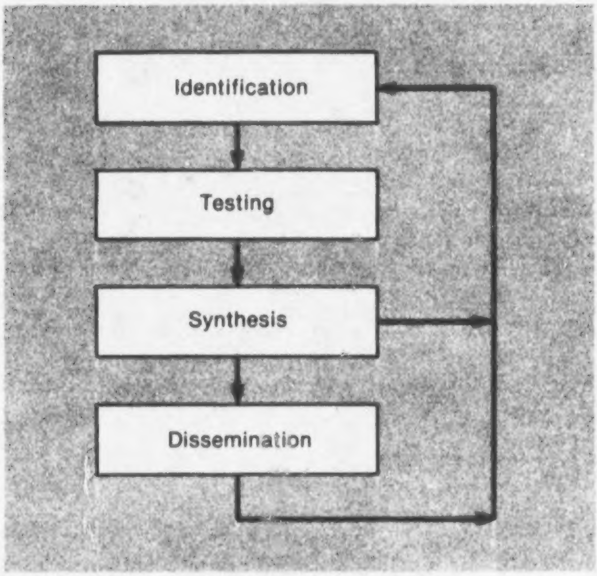
CONCEPTUAL FRAMEWORK FOR MEDICAL TECHNOLOGY ASSESSMENT

Medical technology assessment involves numerous components and subcomponents at various stages of the process. Though these do not exist as a coherent system, discussion of them is facilitated by describing a systematic framework. The multiple components of the medical technology assessment process can be conceptualized as an information flow associated with the following four stages of assessment (see fig. 1):

- *Identification.*—Monitoring technologies, determining which need to be studied, and deciding which to study.
- *Testing.*—Conducting the appropriate analyses or trials.
- *Synthesis.*—Collecting and interpreting existing information and the results of the testing stage, and, usually, making recommendations or judgments about appropriate use.
- *Dissemination.*—Providing the synthesis of information, or any other relevant information, to the appropriate parties who use medical technologies or make decisions about their use.

This four-stage process is applicable to the three classes of medical technologies mentioned earlier—namely, drugs, devices, and medical and surgi-

Figure 1.—Process of Assessing Medical Technologies



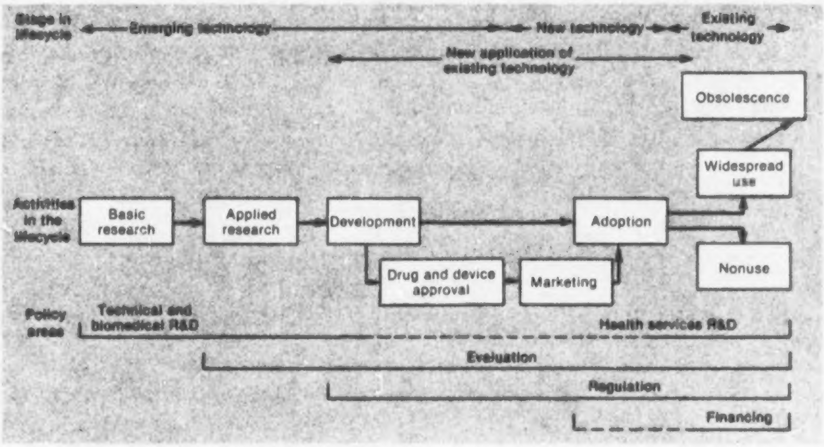
SOURCE: Office of Technology Assessment.

cal procedures. It is also applicable to any technology in any of four typical stages of development, loosely defined as follows:

- *Emerging technology.*—A technology in the phase prior to adoption.
- *New technology.*—A technology in the phase of adoption.
- *Existing technology.*—A technology in general use.
- *New application of an existing technology.*—A new application of a technology in general use.

Visualizing the lifecycle of a hypothetical technology (see fig. 2) makes obvious some of the decision points at which assessment information is essential. If an emerging technology is a drug or device, industry must decide whether to commit resources to develop it; must later decide whether to market it; and must ultimately decide whether to maintain, alter, or discard it. If a new drug or a certain class of device is to be marketed, FDA must decide whether to grant market approval based on safety and efficacy criteria. If the new technology is to be used in medical practice, someone must decide whether to pay for it. In some cases, the Health Care Financing Administration (HCFA) must decide whether to include a new technology or a new use of an existing technology as a reimbursable expense for Medicare beneficiaries. Private insurers, such as Blue Cross/Blue Shield and health maintenance organizations, must make similar decisions. Hospitals must decide whether to purchase, and practitioners and their patients must decide whether to use, the technology.

Figure 2.—Lifecycle of a Medical Technology


Stage in lifecycle
Emerging technology
New technology
Existing technology
New application of existing technology
Obsolescence
Widespread use
Activities in the lifecycle
Basic research
Applied research
Development
Adoption
Nonuse
Drug and device approval
Marketing
Policy areas
Technical and biomedical R&D
Health services R&D
Evaluation
Regulation
Financing

SOURCE: Office of Technology Assessment.

In contrast to drugs and devices, medical and surgical procedures and their variations are ordinarily developed by clinicians and researchers and therefore seldom require investment decisionmaking by industry. Furthermore, under the present system, medical and surgical procedures are not regulated for safety and efficacy by FDA and thus tend to escape the regulatory decisions. Nevertheless, decisions about the use of such procedures must be made.

Many medical technologies in use have not been adequately evaluated. If all medical technologies were adequately assessed as emerging or new technologies, there would be less need for assessing existing technologies.

In addition to considering the stages of the assessment process and the classes and developmental stages of technologies, an assessment system requires the measuring of specified effects. Depending on the technology, the effects to be considered are health (safety, efficacy, and effectiveness), economic, or social. Once the categories of effects to measure have been determined, testing and analysis may begin. Throughout the assessment process, all information and decisions must be balanced against the moral and ethical values of society.

IDENTIFICATION: TECHNOLOGIES NEEDING ASSESSMENT

A decision to conduct a technology assessment must be preceded by the identification of technologies that should be assessed and the setting of priorities among candidate technologies. Identification procedures may vary with the type of technology, but basically can be classified as one of three types: 1) routine mechanisms, 2) priority-setting mechanisms, and 3) mechanisms of opportunity. Routine mechanisms systematically identify a class of technologies, usually in relation to a specific event—e.g., FDA requires that all drugs and devices be registered before they can be marketed or tested in humans. Priority-setting mechanisms are used, as needed, to apply implicit or explicit criteria to determine which technologies should be assessed—e.g., HCFA and the National Institutes of Health (NIH) set research agendas. Mechanisms of opportunity are not formalized but are valuable in identifying technologies as they surface or become important—e.g., patient outcome data may bring the need for analysis to the attention of researchers or the public.

Identifying medical technologies for priority-setting and assessment is an important responsibility primarily of several agencies within the Department of Health and Human Services (DHHS): FDA, the National Center for Health Services Research (NCHSR), NIH, and HCFA. The National Center for Health Care Technology (NCHCT), while it was funded, also identified technologies for assessment.

FDA identifies new drugs and medical devices through its premarket approval authority. To test promising new drugs in humans, drug sponsors (e.g., manufacturers) must notify and receive permission from FDA through a "notice of claimed investigational exemption for a new drug" (IND). If the drug successfully passes this premarket testing, the sponsor may file for a "new drug application" (NDA), which is a request for FDA's permission to market the drug. Since 1962, when this regulatory mechanism was instituted, FDA has reviewed over 13,500 applications for INDs and has approved about 1,000 NDAs. In 1976, FDA was also given expanded responsibility for regulating medical devices. In the first 4 years of implementing the 1976 Medical Device Amendments, about 98 percent of the listed devices in the 10,540 premarket notifications received were claimed to be "substantially equivalent" to preexisting devices. In 1981, FDA estimated that 2,300 premarket notifications would be reviewed. New applications of existing drugs and devices must also meet premarket approval requirements, but the initiative for these new applications remains with the manufacturer, not with FDA. FDA does support some monitoring activities of existing drugs and requires manufacturers to report adverse reactions, but these postmarketing surveillance activities are focused on the safety aspects of these drugs, not on refinements in use or new uses.* Nevertheless, postmarketing surveillance has the potential of becoming an effective method of identifying existing technologies in need of further assessment.

NIH and *NCHSR* are research agencies that identify emerging and sometimes new technologies in need of assessment through their priority-setting processes for research grants and contracts. Projects are selected on the basis of technical merit and whether they are addressing important issues. The processes generate information useful to policy decisions, but do not necessarily address the immediate priorities of operating agencies such as HCFA.

HCFA reimburses for Medicare and therefore has obvious incentives for identifying technologies in need of assessment; nevertheless, it has no mech-

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*This topic is to be explored in greater depth in OTA's forthcoming report, to be published this fall, entitled *Postmarketing Surveillance of Prescription Drugs.*

anisms for the identification of existing technologies in widespread use. For new technologies, the identification is by opportunity. When the question of coverage arises for new technologies, HCFA must determine whether it has adequate information to make a decision and must set priorities for technologies that must be assessed to provide more information. Also, through its Office of Research and Demonstrations, HCFA sets priorities for assessing technologies that are important to its operations.

NCHCT was established in 1978 to undertake and support assessments of medical technology, but did not receive funding in 1982. NCHCT coordinated interagency issues, but also set its priorities internally and had its own responsibilities for identifying technologies. Specifically, NCHCT compiled an annual "emerging technology list" as an early alert system for assessment, but the 1981 reauthorization of NCHCT withdrew its authority to compile the list. (Industry argued that the list threatened innovation by casting doubt on the eventual marketability of a technology.) NCHCT also initiated a plan to develop a joint public-private model for collecting clinical data on emerging technologies. Finally, the NCHCT Director chaired the Technology Coordinating Committee of DHHS, which was the Department's primary mechanism for coordination of issues associated with medical technologies.

Overall, the identification stage of the current system of technology assessment has serious shortcomings. The degree to which current processes identify technologies varies. Emerging and new drugs and devices are adequately identified for assessment prior to their being marketed. However, emerging and new medical and surgical procedures are not adequately identified, because no one in either the private or the Government sector has a clear responsibility for the task. New mechanisms are especially needed to identify for the purpose of assessment existing technologies of all classes, new applications of existing technologies of all classes, and medical and surgical procedures in all four stages of development.

TESTING: TYPES OF INFORMATION NEEDED AND MECHANISMS FOR TESTING

As a basis for decisions, a strategy to assess medical technologies must take into account what is known, what is not known, what is needed, what can be obtained, and at what cost. Information will never be perfect, and money and time will always be limited; thus, evaluation methods must be used judiciously and their results must be interpreted cautiously, in conjunction with numerous other measurements, especially with consideration for society's moral and ethical values. Three categories of information about a medical technology are needed for policy decisions: 1) health effects, 2) economic effects, and 3) social effects. The methods and procedures for determining these effects have strengths and weaknesses closely paralleling those of the identification phase.

Health Effects

Health effects are determined during the testing stage of assessment. The basic questions asked are: Does the technology work? and How well does it work? The former question seeks information about the technology's efficacy and effectiveness, the latter about its safety (and risk). The information provided by analyses of health effects helps decisionmakers determine whether a drug or device should be allowed on the market or whether further investment in R&D is warranted.

Patient outcome is the desired endpoint measured in efficacy and effectiveness analyses; efficacy is tested under ideal clinical conditions, whereas effectiveness is tested under average, or typical, conditions. Tests for effectiveness demonstrate whether efficacy information can be generalized to the population at large. For new drugs and certain devices in the emerging phase, efficacy must be established in preclinical, biochemical, or animal tests before it can be tested among humans. The method that gives the most valid and most reliable information about efficacy is the randomized clinical trial (RCT). The strength of the RCT lies in its randomization process, producing two or more groups that are identical except for chance occurrence, which can be estimated statistically. The drawbacks of RCTs are that they can only be used in certain settings, they are sometimes not ethical to conduct, and they do not always provide complete information about safety.

Thus, despite the highly valid information they can produce, RCTs are not always the method of choice. Other methods can be used as substitutes for RCTs or to supplement them. Observational methods, for example, are designed to analyze data from nonrandomized study designs. Such methods can be useful in ruling out competing explanations for an observed effect and for testing hypotheses in large, diverse populations after a technology is widely diffused. Prospective cohort studies, for example, can be used to detect rare adverse reactions to drugs that were unsuspected prior to marketing. Case-control studies are an inexpensive means of indicating whether the use of a technology results in a small level of risk.

Another, more common type of study is the case study, typified by a physician reporting his or her experience with particular technologies and patients. Case studies are useful in an overall assessment strategy in that they can facilitate the identification of technologies in need of assessment. Case studies are important identification mechanisms of opportunity, as defined earlier. However, the validity of case studies is extremely low because of, among other things, observer bias and the placebo effect. Nevertheless, clinicians are very often swayed by these case reports, which fill the medical literature and which often describe the successful application of a technology.

Safety is measured in terms of a risk-to-benefit ratio; it is therefore a relative concept. The estimation of safety may be a byproduct of testing for efficacy and effectiveness. A low risk may be unacceptable if there is no benefit, but a high risk may be acceptable if the benefits are also high. RCTs tend to give risk information only on a small segment of the population. To generalize to other segments, supplemental information is needed from surveys and methods which can make use of registries and clinical data banks.

For certain technologies, especially devices, establishing the technology's performance integrity is a prerequisite for efficacy assessment. Performance standards usually pertain to the chemical, physical, and electric properties of devices. Similar standards are often used in evaluating technologies which have an intermediate rather than a direct effect on the patient's health outcome, e.g., diagnostic and often prevention technologies. In such cases, the technology is evaluated in terms of its ability to cause one effect that in turn will cause the desired result. For example, an automatic blood pressure monitoring device must accurately measure and record blood pressure if it is to be used for diagnostic purposes.

No precise formula exists for choosing the best or most appropriate evaluation method. The stage of development of the technology itself—e.g., emerging, new, or existing—will partially determine the appropriateness of a method. The purpose of the technology—e.g., diagnostic, therapeutic, or preventive—will limit the range of appropriate methods. However, other factors such as existing knowledge about the risks and benefits and available resources may influence or override otherwise "ideal" choices. The important criterion in selecting analytic methods is not which is theoretically more sophisticated, but which is practically the most appropriate.

Economic Effects

Analytical methods to determine the economic effects of medical technologies comprise a spectrum ranging from sophisticated computer-based data analyses to best-guess estimates of costs and benefits. The broad terms cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA) refer to two techniques for comparing the positive and negative consequences of alternative ways to allocate resources. The principal distinction between the two is that CBA values all costs and benefits in monetary terms whereas CEA produces a measure of the cost involved in terms of some desirable health-related effects (e.g., years of life gained).

Measurements of economic effects should consider both direct and indirect costs. Direct costs are those associated with direct medical care usage: the cost of the physician, the hospital, the medical supplies. Indirect costs are associated with the value of time lost in receiving medical care and in being sick. When indirect costs are considered in economic analyses—and often they are not—they are frequently measured in terms of lost or gained wages.

Economic analysis is complex and must consider more than charges for services. For example, cost analyses should develop information on opportunity cost, marginal valuation, joint production considerations, R&D costs, overhead, costs v. prices, and discounting. Just as no one method is invariably appropriate in the evaluation of health effects, no one method of economic analysis is appropriate. The user of the information will partially determine the kinds of analyses done. For the patient, the actual cost of services is the important information. For policymakers, more complex information is required. In the sequence of the assessment process, information about the economic effects may be useless if reliable and appropriate information about the health effects is not available.

Social Effects

Urgent ethical and social questions are being raised in areas of biomedicine such as experimentation with human subjects, genetic engineering, human reproduction, and the possibly inappropriate prolongation of life. Who is affected by a medical technology? Who is not affected? What values of individuals and society are involved in use of the technology? What ethical principles are involved in testing the technology?

To varying degrees, medical technologies may affect the personal and work lives of patients and their families; influence the structure of medical, legal, and economic systems; and challenge society's most fundamental beliefs. Considerations of the social and ethical implications of medical technologies, therefore, must take an important place in the development of policies. Social implications are the direct or indirect effects of medical technology on the concepts, relationships, and institutions society considers important. Ethical questions in relation to medical technologies—especially those concerning principles of distributive justice, respect for individuals, and benevolence—may also have profound social implications.

Unlike health and economic effects, social and ethical issues do not lend themselves to quantitative measurement and analysis. However, the systematic identification and evaluation of the social impacts resulting from the use of medical technologies can be crucial. A related task is to identify the values that underlie policy alternatives, including moral and ethical values. Systematically assessing values does not necessarily elucidate a single, clear, conclusive answer about which policy to adopt; but, rather, it clarifies the array of choices, the reasons for disagreements, and the compromises required.

A second aspect of assessing values is to make a reasonable inquiry into the values that permeate and underlie the assessment itself. Value judgments enter into every aspect of technology assessment; they determine which technologies will be assessed and at what phase of their development, the scope of assessments, the kinds of data that will be collected and analyzed, the methods of the assessment, and how the assessment findings will be used in decisionmaking. It is important to clarify, therefore, why an assessment of a particular technology was initiated and how it fits into larger cultural and political contexts, what affects the performance of assessment (e.g., the choice of assessors and the analytic goals and methods), and what values affect the application of the results.

Mechanisms for Testing

The major problem with the testing phase of the current assessment system is the lack of a systematic approach for testing identified technologies in all phases of development for all types of required information.

FDA, in its regulatory role, is probably the most significant agency in stimulating technology testing. Most FDA regulation requires industry to test, according to approved protocols, new drugs and many medical devices for safety and efficacy. For drugs, Phase I studies are studies to determine levels of tolerance (toxicity), followed by early dose ranging studies for safety and sometimes efficacy. If safe, the drug can be tested in Phase II studies to demonstrate efficacy and relative safety under controlled conditions. Phase III studies are expanded controlled and uncontrolled clinical trials. If these trials are successful, the company may file an NDA. FDA then reviews the data and may approve the drug for marketing. Since 1962, FDA has approved about 1,000 NDAs. For devices, FDA requires that 90 days notice be given about any new device industry intends to market. If a device does not meet safety and performance standards for its assigned classification, or if adequate information is not available for such a determination, FDA may require testing of the device. For drugs and devices, FDA's assessment activities are generally limited to safety and efficacy and do not involve cost, cost effectiveness, or social effects.

Unlike drugs and devices, medical and surgical procedures are not regulated, and their testing, if done, is through research whose funding comes primarily from NIH and from private foundations. The costs of the later developmental phase of procedures tend to be paid by patients (or by the Government), usually through standard medical insurance policies, even when the procedure has been clearly designated as experimental. Medical and surgical procedures usually begin as user-generated innovations; for example, a surgeon may modify an existing technique during surgery. Increasingly, innovations arise in academic centers, from researchers who know how to present their innovations in a technically acceptable manner at professional meetings and in journals. These researchers' presentations tend to encourage the adoption of innovations without their receiving a routine, formal examination for safety and efficacy.

Whereas FDA regulations affect efficacy and safety, four other regulatory programs are concerned with cost issues: section 1122 review, State certificate-of-need laws, the National Health Planning and Resources Development Act of 1974, and Professional Standards Review Organizations (PSROs). Although HCFA, which makes reimbursement policy, has its own research arm, the Office of Research and Demonstrations, it has seldom conducted technology assessments. NCHCT, an agency legislatively mandated to support comprehensive assessments of health care technologies for all effects (including health, economic, and social), was not funded for 1982.

Social assessment activities have been conducted by several Government mechanisms. OTA was established in 1972 as an analytic support agency to conduct policy research on science and technology issues for congressional committees. OTA's health-related reports have focused primarily on methods available for assessing technologies and issues prompted by their use. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established in 1974 to develop ethical guidelines for conducting research in human subjects. The National Commission produced numerous reports with recommendations, many of which were adopted by DHHS,* particularly those governing the protection of human subjects. The Ethics Advisory Board, which was established in 1978 at the National Commission's recommendation but was not funded in 1980, was mandated to review ethically problematic research protocols and research involving human projects. The board fielded queries from other DHHS agencies such as NIH and the Centers for Disease Control. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research succeeded the National Commission in 1978. Members of the President's Commission are appointed representatives from DHHS, the Department of Defense, the Veterans Administration, the Central Intelligence Agency, the National Science Foundation, and the White House Office of Science and Technology Policy. The President's Commission conducts studies in medical practice and biomedical research and examines five subjects for legal and ethical implications: informed consent, privacy, uniform definition of death, genetic issues and unborn humans, and availability of health services. NCHCT's responsibilities, as mentioned above, included assessment of the ethical, legal, and social implications of medical technologies.

SYNTHESIS: USING INFORMATION AS THE BASIS FOR DECISIONS

Synthesis of the information generated during the testing stage of the assessment process is the necessary step to providing a convincing and responsible basis for decisions made during all phases of a technology's lifecycle.

The synthesis activities that pertain to medical technology assessment fall into two broad areas: 1) synthesis of the results of individual research studies; and 2) synthesis of a body of research findings with various concerns such as risk, social, ethical, or cost factors. The first type of synthesis addresses questions of safety, efficacy, or effectiveness of a given technology; the latter is more policy oriented, often seeking to set guidelines or standards for medical practice or reimbursement policy. The value of the latter depends, in large part, on the adequacy of the former.

Synthesis of Research Findings

The traditional approach to synthesizing research information is the literature review, an article summarizing the data of those studies a reviewer believes to be the most relevant to the topic under review. Literature reviews are useful and heavily relied on, but because of their scope and the delays in the journal publication system, such reviews are rarely timely, especially in reporting an ineffective or unsafe technology. Furthermore, the reviews are subjective and often have no commentary on methodological problems in individual studies.

More systematic procedures for integrating and interpreting sets of research evidence do exist and can be employed. The most simple technique is a simple classification technique, sometimes called the "voting method." This technique involves selecting a sample of evaluative studies, coding some aspect of the design, classifying outcomes as favorable, neutral, or unfavorable and constructing tables of research findings. The method identifies methodological strengths and weaknesses among studies and can help determine patient populations and under what conditions they are most likely to benefit from a technology.

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*Then the Department of Health, Education, and Welfare.

Meta-analysis is a technique that assesses the magnitude of treatment impact by quantitative comparison of actual study results. This method is particularly useful in assessing treatments for which a large number of studies are available and findings across studies seem to have great variability. However, it may have drawbacks with respect to sample selection.

Currently, no single technique is fully adequate for synthesizing research; however, the application of formal quantitative procedures is beginning to give a better understanding of methodological problems in research itself. Formal procedures can segregate differential outcomes according to treatment characteristics and methodological approaches. Contradictions can then be identified, analyzed, or further researched. In the performance of formal quantitative analyses, an important suggestion is that the significance of the results should be interpreted and reported in language that is useful to decisionmakers.

Synthesis of Health, Economic, and Social Effects

How, then, does one bring together and synthesize all information available about all three categories of the effects of medical technologies—health, economic, and social? Once specific information has been synthesized through various methods in each of these realms, how can a decisionmaker balance the values and interpret them into programmatic actions?

OTA's report on CEA concluded that performing an analysis of costs and benefits can be very helpful to decisionmakers, because the process of analysis gives structure to a problem, allows an open consideration of all relevant effects of a decision, and forces the explicit treatment of key assumptions. Formal techniques such as CEA can be used to aid in the synthesis of information concerning the health and economic effects of a technology. OTA found, however, that although CEA can be useful as a decision-assisting tool, it exhibits too many methodological and other shortcomings for the numerical results to be used as the basis of policy or program decisions. For example, although CEA can be used to synthesize information concerning health and economic effects, it cannot in itself adequately address social and ethical issues. These have to be addressed more fully by other means.

The most appropriate approach to any assessment is to perform it in an open forum so that assumptions and underlying values can be challenged; to identify, measure, and, to the extent possible, value all relevant benefits/effects and costs; and to present the results of the analysis as an "array" of benefits/effects and costs rather than forcing the results into a single aggregate measure. By arraying effects in a systematic fashion, one can place the appropriate relative emphasis on given effects whether they are quantifiable or not. This technique is designed to make more explicit the health, economic, and social consequences of any decision.

Synthesis of Opinion

Synthesis of information may occasionally present a clear-cut indication of the next stage of assessment or phase of technology development. More likely, uncertainty will still predominate for decisionmakers. The uncertainty may reflect the presence of random events or may reflect a basic lack of knowledge. The former can be analyzed by various statistical techniques: decision analysis, confidence limits, computer simulation, sensitivity analysis. However, these techniques cannot actually resolve policy controversies or substitute for informed judgment.

Policy judgments may require a synthesis of opinion which can be solicited from groups and expert input. The most common format of soliciting group opinions is the unstructured conference which may involve presentations, discussions, and debates. Another informal technique is the advisory panel approach used by many Government agencies. The four best known formal techniques used in medical contexts for resolving conflicts and uncertainty are: 1) the Delphi technique, 2) the nominal group process technique, 3) the consensus development conference (NIH), and 4) a computerized knowledge base which maintains expert opinion on the state of the art of a specific topic (e.g., the Hepatitis Knowledge Base of the National Library of Medicine, NLM). Although these formal techniques produce more reliable opinion information than an unstructured conference does, evidence of effectiveness is contradictory for the Delphi and nominal group processes and sparse for the NIH and NLM processes.

DISSEMINATION OF INFORMATION

What potentially are the direct effects of dissemination of assessment information? Who should have top priority in receiving information? How should the information be disseminated? The dissemination of assessment information directly affects the development and diffusion processes of medical technologies. The consideration of whether to disseminate information is therefore weighty. If a decision is made to disseminate information because the technology is deemed either worthy or unworthy of its next phase of development, the information must reach, at a minimum, the decisionmakers involved with the technology in any aspect of its use. That audience may range from directors of R&D in private industry, to health professionals, to the general public. Reaching the audience in a timely manner requires a systematic approach to information dissemination, especially in view of the pace and quantity of information development and the lack of mechanisms for the systematic synthesis of information. In a sense, the information available is at once too much and too little.

Government Activities

The Federal Government produces, collects, and disseminates assessment information. NCHSR, for example, disseminates the results of health services research to relevant Government agencies, the research community, and other interested parties through publications, press releases, conferences, and workshops. In 1978, the legislation authorizing NCHSR was modified to require that at least $1 million or 5 percent of its budget, whichever is less, be used for dissemination activities. In response, NCHSR established a User Liaison Program to provide substantive assistance to non-Federal health care leaders concerned with critical policy issues and operational problems in the organization, administration, regulation, and delivery of health care services at State and local levels.

Monitoring NIH's dissemination activities is the responsibility of the Office for Medical Applications of Research (OMAR), established in 1978 in the NIH Office of the Director, and assisted by the OMAR Advisory Committee. One important mechanism for dissemination is the consensus development conference. The synthesis of opinion that is achieved at a consensus conference is presented in consensus statements and supporting materials which are distributed to practicing physicians, other health professionals, the biomedical research community, and the public—through a mailing list of over 21,000 names. Also, members of the press are invited to the conferences and are encouraged to publish the results. Leading medical journals and medical societies have published the consensus materials.

In conducting medical technology assessments, information from several subject areas is often required. A common need in most assessments, however, is for information from the field of biomedicine. NLM is the major Federal library resource for biomedical literature. It is the predominant creator and disseminator of biomedical bibliographic information. NLM's coverage of the health services literature is less comprehensive than its coverage of the biomedical literature, in part because relevant health services information appears in so many diverse documents.[2] Another source of information for medical technology assessments is the National Technical Information Service (NTIS). NTIS is the central repository for scientific and technical information generated by federally funded R&D projects, including those in DHHS.

Other Mechanisms

Apart from formal Federal agency activities, mechanisms for dissemination include the public media, the mail, advertising, personal contacts, the educational process, libraries, and other types of information centers. The appropriateness of any of these mechanisms depends on whether the information is to be used in assessing or marketing a medical technology. Print media, radio, and television are primary channels to the public. In addition to carrying news about medical technologies and issues, they increasingly tend to have health columns and special in-depth features about health technologies. For more targeted audiences, mailings are used for solicited and unsolicited information dissemination, for example, newsletters from drug companies, advertisements from product distributors, and Federal literature. Advertising of drugs occurs in all media for the public and for health professionals. A recently developed form of advertising, the video cassette, is supplied to medical facilities. Personal contacts are an especially credible source of information exchange among health professionals. These often occur formally and informally at professional meetings.

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[2] This topic is to be explored at greater length in a separate OTA technical memorandum entitled *MEDLARS and Health Information Policy*, to be published in fall 1982.

MAJOR CONCLUSIONS OF THE STUDY

In this study of medical technology assessment, OTA has reviewed the evidence and concludes overall that there is no coherent system of assessing medical technologies. There is, however, an urgent need for such a system. The following are capsule statements of OTA's conclusions about the adequacy of the present system with respect to the four stages of technology assessment presented in figure 1: identification, testing, synthesis, and dissemination.

Identification

Emerging Technologies

OTA concludes that emerging drugs and devices are adequately and appropriately identified, but that emerging medical and surgical procedures could be better identified. Overall, however, the identification of emerging technologies for assessment is not a critical weakness of the present assessment system.

New Technologies

OTA concludes that new drugs and devices are adequately identified for the purposes of assessment, but that new medical and surgical procedures are not. The most pressing need is for some routine mechanism, e.g., the reimbursement system, to identify new procedures before they are widely adopted. The reimbursement system may be the prime candidate, because coverage and payment decisions are critical points in the diffusion of many technologies. The priority-setting systems of the institutes of NIH and of other Federal research agencies (e.g., NCHSR) are adequate and appropriate for their respective mandates, but there is not an adequate similar system to fulfill the needs of operating agencies (e.g., HCFA, planning agencies). Finally, sufficient mechanisms of opportunity for identifying new technologies could be developed. Medical specialty societies could be helpful in this area.

Existing Technologies

OTA concludes that the system for identifying existing technologies in need of assessment is inadequate. The most promising possibility for identifying such technologies may be FDA's postmarketing surveillance of marketed products. In the case of existing as well as new technologies, the priority-setting procedures of Federal research agencies may be adequate for those agencies' respective needs; however, these procedures are not adequate for the needs of operating agencies such as HCFA. And the operating agencies themselves do not adequately identify existing technologies for assessment. Medical specialty societies could be helpful in this area. Finally, NCHCT's activities of identifying nationally important priority technologies for assessment were valuable but are not currently funded. Thus, no organization is currently performing this important task.

New Applications of Existing Technologies

OTA concludes that new applications of existing technologies in need of assessment are not adequately identified. The most promising approach would seem to be the use of the reimbursement system to link the diagnosis with the use of technology. Medical specialty societies could be helpful in this area.

Testing

OTA concludes that, in general, drugs and devices are adequately tested for safety and efficacy prior to being marketed. Medical and surgical procedures, which often include the use of drugs and devices within the practice of medicine, are not well tested for either safety or effectiveness. No class of technologies is adequately evaluated for either cost effectiveness or social and ethical implications. Finally, there is no organization whose mission it is to ensure that medical and surgical procedures are assessed for safety and efficacy or to evaluate medical technologies for cost effectiveness and for social/ethical effects.

Synthesis

OTA concludes that the synthesis phase of the present system of technology assessment is unnecessarily weak, within both the private and public sectors. Research evidence regarding the safety, efficacy, and effectiveness from the use of medical technologies is seldom examined systematically and objectively. Federal agencies and private insurers and organizations set policies, guidelines, regulations, and/or make reimbursement coverage determinations, many of which profoundly affect the adoption and level of use of medical technologies. Yet, their decisions are usually based on informal, subjective, group-generated norms which tend to support the status quo. Formal, more objective techniques do exist, however, not only for evaluating research evidence but also for making decisions and setting policy. These techniques could be used more often to aid in better decisionmaking.

Dissemination

OTA concludes that better methods need to be found to communicate information about medical technologies to health practitioners, health researchers, and health policymakers.

OTA also concludes that Government-generated research reports, many of which may be important to technology assessment, are not as accessible as they could be. Finally, NLM's mission and capabilities should be examined to determine whether more Government reports and nonserial literature should be included in its data base, and whether NLM should index articles differently for researchers interested in technology assessments.

POLICY OPTIONS

The most important policy need is to bring forth a rational, systematic approach from the present multiplicity of agencies and activities to promote and coordinate medical technology assessment. This could be accomplished in any of several ways. The options listed below are divided into two broad categories: legislative and oversight. OTA finds that there are relatively few realistic legislative options necessary for Congress to consider, primarily because there is already substantial power invested in the Secretary of Health and Human Services to develop a coherent system of medical technology assessment. Thus, in most of the deficient areas noted within this report, congressional oversight may be sufficient.

Legislative Options

1. Sponsor or grant a charter to a private/public organization to undertake medical technology assessment activities.
2. Maintain the authority of, and appropriate funds for, NCHCT.
3. Change the statutes so that HCFA can selectively reimburse for experimental technologies in return for clinical data.
4. Increase funding to train researchers in methodological and statistical principles.
5. Increase efforts to train health professionals in methodological and statistical principles.

Oversight Options

6. Encourage the private sector to take the lead in assessing medical technologies.
7. Examine how Federal research institutes (e.g., NIH), agencies (e.g., NCHSR), and research programs of operating agencies within DHHS could identify technologies better when setting research agendas; and how the PSRO program and the reimbursement system could be used to more advantage for identifying technologies for assessment.
8. Continue to conduct oversight hearings concerning the duplication and fragmentation of health-related data collection activities.
9. Examine the ability of operating agencies within DHHS (e.g., HCFA) to generate sufficient information for their own decisions related to medical technologies, and examine the extent to which the Secretary of

Health and Human Services utilizes the department's other research arms (e.g., NCHSR, NIH) to procure that information in a timely manner.

10. Examine the activities, plans, and potential for elements of DHHS (e.g., NIH) in utilizing various research methods to determine the appropriate use of medical technologies.
11. Explore how research evidence could be better evaluated by Federal health agencies when recommending, setting, or implementing health policy.
12. Examine the disposition of federally generated reports to determine how accessible and useful they have been both to private and public researchers and policymakers.
13. Examine whether NLM should include more Government research reports and other nonserial literature in its MEDLARS data bases.
14. Encourage use of the powers vested in the Secretary of Health and Human Services to develop a coherent system of medical technology assessment.

NOTE: Copies of the full report "Strategies for Medical Technology Assessment," can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, GPO stock No. 052-003-00887-4.

Mr. GORE. I would like to thank you for your testimony here today, too, Dr. Banta. Thank you very much.

Dr. BANTA. Thank you very much.

Mr. GORE. Now, our final panel is a large panel. I would like to ask them to come to the witness table, and we will get some additional chairs if necessary.

Dr. Jeffrey Prottas, visiting professor at the Center for Health Policy Analysis and Research at Brandeis; Dr. Richard Rettig, professor and chairman of the Department of Social Sciences at the Illinois Institute of Technology in Chicago; Dr. Peter Safar, university professor at the University of Pittsburgh Resuscitation Research Center; Dr. Kenneth W. Sell, founder and past president of the American Association of Tissue Banks; and Winifred B. Mack, president of NATCO at Stony Brook in the Department of Surgery of Long Island. NATCO, of course, is the North American Transplant Coordinators Organization, and we are happy to have Winifred Mack join us today.

Without objection, as I stated earlier, all of your prepared statements will be included in the record in full.

We will start with Dr. Kenneth W. Sell, founder and past president of the American Association of Tissue Banks in Rockville, Md.

Dr. Sell, welcome and please proceed.

STATEMENT OF KENNETH W. SELL, M.D., PH. D., AMERICAN ASSOCIATION OF TISSUE BANKS

Dr. SELL. Thank you, Mr. Chairman.

I am pleased to appear before you and the committee to talk about these important issues.

The American Association of Tissue Banks was established specifically to deal with a broad range of interests and issues related to tissue procurement and preservation.

The objectives of this organization have been to promote scientific and technical research and knowledge regarding both the donor procurement and collection as well as the processing and storage and transplantation of all forms of transplants, including cells, tissues, and organs.

We have also been trying to encourage voluntary donation of organs and tissues and to encourage the development of regional tissue banks to provide these materials in a safe and adequate and economical supply.

The advances that we have read about in the literature and heard at this committee meeting have shown us that we have a new wave of transplantation upon us. In large part, we have heard that this reflects improvements in immunosuppressive techniques such as the use of cyclosporin.

What is perhaps not fully appreciated is that immunosuppression even with cyclosporin is only a stage in the development of the transplantation issue. It still represents a nonspecific immunosuppressive agent which does have side effects, as all nonspecific immunosuppressive agents have.

That does not mean that cyclosporin is not a significant, important, and very valuable contribution to transplantation. But we must realize that research is currently ongoing that within the next decade lead to complete abolition of graft rejection, either through treatment of the graft by eliminating stimulating leukocytes or through pretreatment of the recipient to induce tolerance, just as a mother induces to her own child that does not reject it.

At the present time, the number of candidates for organ transplantation is limited in part, at least, by the capacity of the recipient to tolerate the various immunosuppressive regimens that are available. Because of the risks involved, organ transplants are usually limited, therefore, to those for whom it is a life-saving procedure.

The prevention of graft rejection and the elimination of the need for immunosuppression will ultimately make transplantation feasible for the treatment of non-lethal conditions and will vastly increase both the number of candidates for transplants and the varieties of organs and tissues to be transplanted. We must look ahead to an explosive increase in demand for organs and tissues.

The dramatic, life-saving nature of organ transplants has often obscured the fact that a variety of other tissues are now used successfully in reparative surgery in patients with a wide variety of clinical conditions. These tissues are generally preserved by freeze-drying and are nonviable. They provide structural support and serve as matrices for repopulation of host cells.

For example, less spectacular to the public, although not to the patient, is the removal of an osteosarcoma, a bone tumor, with its replacement by a cadaver joint or bone graft. Such patients in the past routinely required amputation in order to effectively and completely remove the bone tumor.

Now, through the pioneering work of surgeons such as Dr. Henry Mankin of Harvard, it is often possible to remove the tumor and replace the neoplastic tissue with normal allograft cadaver bone.

There are over 40,000 bone transplants done in this country each year in which bone is taken from one part of the body and used in another. Each of these could be considered for allograft bone transplantation if sufficient donor tissue were available.

We already know that corneal transplants are used widely since the first eye banks were established in 1944. Restoration of sight, while not lifesaving, is a significant personal event.

Other transplantable tissues include tendons, cartilage, heart valves, fascia, dura, arteries, nerves, bones of the inner ear and skin. Skin is used primarily for the treatment of burn patients as a temporary dressing, allowing them to survive until their own skin can be used for definitive covering.

In order to successfully and adequately deal with the national transplantation program, both the public and the scientific and medical professions must engage in a cooperative effort. Individual citizens are ultimately the source of donor material, and we must develop a national awareness of the critical importance of organ and tissue donation as a civic and humanitarian responsibility.

However, perhaps equally or more important is cooperation within the medical profession. Each tissue and organ has its own protagonists, working diligently to develop the most successful transplant schemes possible to provide the best medical care for their patients.

However, surgeons and others involved in cell, tissue, and organ transplantation must also recognize that all tissue comes from a common donor source. If we are to maximize the availability of tissues and organs, we must not unduly emphasize the importance of one versus the other.

Without question, those lifesaving procedures requiring organs that can be stored for only a few hours must deserve top priority. However, it is notable that in many communities, the eye bank, the skin bank, the bone bank, and the kidney transplant bank may seek independently to obtain tissues or organs necessary to meet the needs of their clinical specialty.

On the other hand, we have excellent examples recently being developed of cooperation in various cities such as Baltimore, Miami, St. Louis and San Francisco, where the various groups of specialized surgeons and transplantation organizations are working together.

We would appreciate your committee's efforts to ensure that the Federal Government supports, but does not bias, the development of this cooperative regional effort to collect tissues and organs. Preferential funding of transplantation of a particular organ could lead to an undue emphasis which might preclude or at least interfere with the procurement of other valuable tissues.

On the other hand, support for regional procurement facilities allows the altruistic and enlightened physicians to join with their colleagues in providing an expanded source of donor material for all types of transplantation.

We must encourage the private sector to develop regionally cooperative tissue and organ collection and preservation systems and programs. The rapidly accelerating success of tissue transplantation for the treatment of serious and lethal human diseases will inevitably result in a critical shortage unless this cooperative is achieved.

We therefore recommend several items to be considered: First, that this committee and the public in general recognize the total need for transplant tissues in the treatment of both debilitating as well as lifesaving conditions.

We should develop a nationally coordinated program of public education and a large-scale enlistment of individuals committed to donating their organs and tissues at the time of death.

We should facilitate and optimize the methods by which suitable donors are identified in order to maximize the supply of tissue. In this regard, by the way, we heartily applaud the Surgeon General's conference which deals specifically with this issue.

We should try to balance our enthusiasm and support to insure that all forms of transplantation receive the necessary priority for donor collection and transplantation.

We should foster the efforts of the private sector to develop regional cooperation in the collection and preservation of tissues and organs. We would urge the implementation of the centers for disease control pilot program for regional hospital cooperation in the identification of donors through regional tissue and organ banking systems.

And finally, we would suggest that all private sector societies, organizations, research groups, and clinical associations should individually contribute to the effort to identify suitable donors at the time of death. These groups should make information available on the full array of tissues and organs that might be suitable for reparative and life-saving surgery, and not restrict their efforts to parochial interests.

Mr. Chairman, I thank you for the opportunity to address the committee on these important issues.

[The prepared statement of Dr. Sell follows:]

TESTIMONY

by

KENNETH W. SELL, M.D., Ph.D

American Association of Tissue Banks

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear before you to discuss the goals and the commitment of the American Association of Tissue Banks. I am Dr. Kenneth W. Sell, Past President and present member of the Executive Committee of the American Association of Tissue Banks. This testimony reflects both my views and those of Dr. Harold T. Meryman, current President of the American Association of Tissue Banks.

The objectives of the American Association of Tissue Banks are to promote scientific research and technical knowledge regarding the procurement, processing, storage, transplantation, and evaluation of cells, tissues and organs for clinical and research uses; to encourage voluntary donation of these materials; to encourage the development of regional tissue banks to provide a safe, adequate and economical supply of cells, tissues and organs; and to establish guidelines and standards for their collection, preservation and distribution. The Association consists of individual as well as institutional members.

During these hearings, we have heard and been moved by the appeals of those who are concerned with the transplantation of whole living organs, particularly the liver. Patients, their families and their physicians have all expressed their desire to extend the availability of liver transplants, particularly for the correction of hepatic birth defects. The plaintive appeal of the infant must be answered. We understand that the Public Health

Service will shortly be holding a consensus development conference which should permit a valid analysis of the current clinical applicability of liver transplantation in this country. In addition, we are also aware of the improved success of other organ transplants, particularly of kidneys. Several thousand lives are being saved each year because of the success of this technology.

These advances reflect, in large part, improvements in immunosuppressive techniques, especially the use of Cyclosporin A. What is perhaps not fully appreciated is that immunosuppression, even with Cyclosporin, is only a stage of development and that current research in transplantation immunology may, in only a few years, lead to the complete abolition of graft rejection, either through treatment of the graft to eliminate stimulating leukocytes or through pretreatment of the recipient to induce tolerance, just as a mother develops tolerance to her phenotypically different fetus.

At the present time the number of candidates for organ transplant is limited by the capacity of the recipient to tolerate the immmunosuppressive regimen. Because of the risks involved, organ transplants are limited to those for whom it is a lifesaving measure. The prevention of graft rejection and the elimination of the need for immunosuppression will make transplantation feasible for the treatment of non-lethal conditions and will vastly increase both the number of candidates for transplants and the variety of organs and tissues to be transplanted. We must look ahead to an explosive increase in demand.

The dramatic, life-saving nature of organ transplants has often obscured the fact that a variety of other tissues are now used successfully in reparative surgery in patients with a wide variety of clinical problems. These tissues are generally preserved by freeze-drying and are non-viable. They provide structural support and serve as matrices for repopulation by host cells. Of particular value is the fact that freeze-drying destroys the capacity of these tissues to stimulate rejection and no immunosuppressive therapy is required.

For example, less spectacular to the public, although not to the patient, is the removal of an osteosarcomatous bone tumor with replacement by cadaver joint or bone. Such patients, in the past, routinely required amputation in order to effectively and completely remove the tumor. Now through the pioneering work of Dr. Henry Mankin at the Massachusetts General Hospital in Boston, it is often possible to remove the tumor and replace the neoplastic tissue with normal allograft cadaver bone. Over 40,000 bone grafts using bone from elsewhere in the patient are done each year. Each of these could be considered for allograft bone transplantation if sufficient donor tissue were available. We already know that corneal transplantation has been highly successful since the first eye banks were established in 1944. Restoration of the sight, while not lifesaving, is a significant personal event.

Other transplantable tissues include tendons, cartilage, heart valves, fascia, dura, arteries, nerves, the bones of the inner ear and skin. Living skin is commonly used as a covering for extensive burns. It provides a living cover for the burn for four to six weeks until it is rejected, by which time the patient has stabilized and grafts from unburned areas can be applied. Although there are some synthetic coverings that are also used in burn therapy, the future abolition of graft rejection will mean that skin transplants will be permanent and far more desirable than other temporary coverings. Demand will increase many-fold.

In order for a successful and adequate national transplantation program to develop, both the public and the scientific and medical professions must engage in a cooperative effort. Individual citizens are ultimately the source of donor material and we must develop a national awareness of the critical importance of organ and tissue donation as a civic and humanitarian responsibility. Cooperation within the medical profession is equally vital. Each tissue and organ has its own protagonists, working diligently to develop the most successful transplant schemes possible to provide the best medical care for their patients. However, surgeons and others involved in cell, tissue and organ transplantation must also recognize that all tissues come from a common donor source. If we are to maximize the availability of tissues and organs, we must not unduly emphasize the importance of one versus another. Without question, those lifesaving procedures requiring organs that can be stored for only a few hours deserve top priority attention. However, it is notable that in many communities the eye bank, the skin bank, the bone bank and the kidney transplant organ procurement agency seek independently to obtain the tissues necessary to meet the needs of their clinical specialty. On the other hand, we do have excellent examples of cooperation between tissue procurement activities. The Medical Eye Bank of Baltimore, for instance, working closely with the local community, is currently developing plans to facilitate organ donation. The St. Louis Red Cross Blood Center is currently engaged in an effort to coordinate organ, tissue and bone marrow procurement groups, in addition to procuring bone and corneas.

We would appreciate your Committee's effort to ensure that the Federal Government supports but does not bias the development of cooperative regional efforts to collect tissues and organs. Preferential funding of transplantation of a particular organ could lead to an undue emphasis which might preclude, or at least interfere with the procurement of other valuable tissues. On the other hand, support for regional procurement facilities allows altruistic and enlightened physicians to join with their colleagues in providing an expanded source of donor material for all types of transplantation. We must encourage the private sector to develop regionally cooperative tissue and organ collection and preservation programs. The rapidly accelerating success of tissue transplantation for the treatment of serious and lethal human diseases will inevitably result in a critical shortage unless such cooperation is achieved.

I would suggest that this Committee and those who attend these hearings should consider the following:

1. We should recognize the total need for transplantable tissues for the treatment of both reparative and life-threatening illnesses.

2. We should develop a nationally coordinated program of public education and large-scale enlistment of individuals committed to donating their organs and tissues at the time of death.

3. We should facilitate and optimize the methods by which suitable donors are identified in the hospital to maximize the supply of tissues and organs.

4. We should try to balance our enthusiasm and support to ensure that all forms of transplantation receive the necessary priority for donor collection and transplantation.

5. We should foster the efforts of the private sector to develop regional cooperation in the collection and preservation of tissues and organs. We would urge the implementation of the Centers for Disease Control pilot program for regional hospital cooperation in the identification of donors through regional tissue and organ banking systems.

6. All private sector societies, organizations, research groups and clinical associations should contribute to the effort to enlist organ donors, to identify suitable donors at the time of death and to make information available on the full array of tissues and organs that may be suitable for reparative transplantation surgery.

Mr. Chairman, I thank you for the opportunity to address the Committee on this very important issue.

Mr. GORE. Thank you very much.

We will hold our questions until the panel has concluded.

Our next witness is Dr. Peter Safar, university professor at the University of Pittsburgh Resuscitation Research Center.

Dr. Safar, am I pronouncing your name right?

Dr. SAFAR. Yes, you are.

Mr. GORE. Good; welcome, please proceed.

STATEMENT OF PETER SAFAR, M.D., UNIVERSITY PROFESSOR AND DIRECTOR OF RESUSCITATION RESEARCH CENTER, UNIVERSITY OF PITTSBURGH

Dr. SAFAR. Since I am not a transplant surgeon, not a transplant organizer, and not an administrator, I have no vested interest with this testimony.

I believe I am here because I am engaged full time in the research on acute dying processes and resuscitation and because my associates and I developed America's first physician-staffed intensive care unit, and critical care involving training programs, and did research which coinitiated cardiopulmonary resuscitation, brain resuscitation, and orderly brain death certification.

The latter was pioneered by my associate, Dr. Grenvik, who, to my knowledge, was the first one to implement these procedures in the USA in an orderly fashion. In 1968, soon after the Harvard criteria for brain death certification were published, a local committee in Pittsburgh at the same time spelled out such criteria for implementation.

I have some personal experience with the occurrence of brain death and organ donation in my own family. In 1966, my 12-year-old daughter, a chronic asthmatic, asphyxiated to cardiac arrest, in her parents' absence. The heart was restarted, but, her brain remained dead. In order to add meaning to her life and death and to help change the then unsound practices of non-heart-beating cadaver kidney transplants, I gave permission—to my knowledge, for the first time—for the removal of organs before cessation of heartbeat and the discontinuation of mechanical ventilation.

Some comments about recipients. For end-stage renal failure, about 62,000 patients are presently on chronic dialysis in this country. About 5,000 patients received kidney transplants last year in the USA, in spite of the fact that transplants are more cost effective than dialysis.

In Sweden, about 600 patients are on chronic renal dialysis, while almost the same number received kidney transplants in 1 year. The difference between these two countries' ratios is attributed to our country's economic incentives for dialysis.

You are aware of the fact that my colleagues in Pittsburgh, Drs. Bahnson, Starzl, and Hakala, are very active in transplanting hearts, livers, and kidneys. Even the very daring heart-lung combination transplant has been tried there, with 2 out of 4 patients apparently now well at home.

The kidney transplantation procedures, in my opinion, have become an important part of general lifesaving medicine. This will soon be followed by heart, liver, and heart-lung transplants getting this kind of ranking, which, however, at the present time, we should consider innovative therapy. I am deliberately differentiating between innovative therapy, experiments, and research. Not all research is experimental. One should pay through public funds and insurances for innovative therapy. But one should do this in special centers where research can be conducted at the same time.

There has been much said today about whether transplant surgery is experimental or not. Almost every management of a critically ill or injured patient is an experiment. The results of the Pittsburgh group ranged between 50 and 60 percent of the heart and liver transplant patients having survived without organ rejection for up to 1 year or more.

We should look into the future. Once the immune rejection problem is solved, the need for multiorgan donors may increase to 50,000 or 100,000 per year in the U.S.A. About 50 percent of the 62,000 patients with end-stage renal failure now on dialysis, namely 30,000, are estimated to be suitable recipients. The number of candidates for heart transplants may become even greater in the future. Transplantations of hearts can be expected to mushroom once the operative mortality and rejection rate drops below about 20 percent. I fully agree that Cyclosporin has been only a halfway breakthrough, and that we are still far from the solution of the rejection problem.

Most likely, artificial heart devices will prove to be effective for temporary artificial circulation, while the patient with a failing heart is being evaluated as to the recuperability of his own heart or suitability for transplantation. Transplanted hearts seem to adapt better than presently available artificial hearts to changes in functional demands. Heart transplants and liver transplants already give a fair chance for return to good quality of life.

It is very important to assess benefits in terms of quality and duration of survival, not merely in terms of mortality, and to assess the therapies we are talking about in terms of "appropriateness," not so much whether it is experimental therapy or not.

Transplantation surgery should receive public funding, but with consideration of other still-unmet health care needs nationwide. It is nice to be concerned about one child here and another one there. But let's face facts. We have not given high priority to measures which might be more cost effective, such as control of malnutrition, death, and crippling from trauma and infectious diseases; prevention of atherosclerosis; and many others. Our resources are finite.

Some comments about donors. Transplantation of viable organs requires procurement of organs from brain-dead cadavers with the heart kept beating by a breathing machine. To meet the abovementioned needs, methods will have to be found to increase the procurement of organs suitable for transplantation.

In recent years, organs were procured from only about 2,500 brain-dead donors per year in the U.S.A. The estimated maximal number of brain-dead donors presently available seems to be around 20,000 per year.

Certification of brain death is now possible with a safe and orderly process and a 100-percent reliability. This process, however, is not always followed, as illustrated by an occasional patient in the past transferred to our hospital for organ transplantation with the outside diagnosis of brain death, in whom the prescribed orderly reexamination revealed that he was not brain dead, and continued life support resulted in recovery.

There also seem to be physicians who, because of not wanting to be bothered or because of fear of malpractice suits, shy away from initiating brain death certification and rather let nature take its course. This is costly. Therefore, an educational campaign for health professionals is indicated.

Voluntary donation by family members has posed no major problems in Grenvik's experience. The majority of families approached at the time of brain death certification considered organ donation a positive act, to give the life and death of the deceased additional meaning. These positive feelings were seen in spite of shock and grief.

Nevertheless, about 1 of 5 families of potential donors approached by others have refused donation. Hesitancy on the part of primary physicians to approach the family during shock and grief, when he the physician has a feeling of failure in the face of the patient's demise, understandably adds to a low organ procurement rate.

Donor cards have not been the answer. Sigmund Freud said that our own death is indeed unimaginable, so people prefer not to plan for it.

We might increase the number of available donors by medicare reimbursement schemes and by Joint Commission of Accreditation of Hospitals requirements as well as State hospital accreditation requirements changes, particularly to facilitate the brain death certification procedure and to facilitate the transfer of heart-beating cadavers with mobile intensive care unit ambulances to transplantation centers.

But all this might be simpler with "presumed consent for autopsy and organ donation." It is interesting that in Austria, already in the 1700's, a law was introduced by the Emperor which enabled doctors to perform autopsies on patients who died in hospitals, to determine the cause of death and enhance scientific knowledge, without having to ask for consent.

This presumed consent for autopsy, as you know, has recently been extended to presumed consent for organ donation, in Austria, Czechoslovakia, Denmark, France, Israel, Poland, and Switzerland. There is a trend that other European countries will follow, as presumed consent has been recommended by the European Committee on Legal Cooperation, which is equivalent to our National Conference on Uniform State Laws. The family can object. This, in the case of the above-mentioned countries, has happened very rarely.

In my opinion, automatic permission for hospital physicians to carry out autopsies and organ donation without having to first solicit consent from the family, would facilitate measures which are in the public interest, but may cause a backlash in this country, because of our deeply rooted voluntarism. Before embarking on a promotion of presumed consent legislation, it may be wise to carry out an opinion poll to assess such a backlash, which would result in increased public refusal of organ donation.

Organ preservation at the present time is in a very primitive state. Research is needed and should be funded. If organs removed from heart-beating cadavers could immediately be plugged into an effective, not-yet-developed preservation system which would keep them alive for up to 1 week, one could not only make use of perhaps 20 percent more organs than is now the case from presently available donors, but also reduce the cost and manpower drained away from other parts of medical care. Improved organ preservation would change these now-emergency transplant operations into planned elective procedures.

And finally, a comment on cerebral death—neocortical death—which must be differentiated from brain death. Cerebral death—as, for example, in the case of Karen Quinlan—is a condition in which the higher thinking centers of the brain are destroyed, but midbrain, cerebellum, and medulla may still partially be active. These patients may breathe spontaneously, do not show some other signs of brain death, but are unresponsive, and have no chance to recover human mentation.

Biomedical ethics, in my opinion, should not only equate brain death but also cerebral death, namely persistent vegetative state—with emphasis on proven persistence—with death. This, then, would create not only heart-beating but also naturally breathing cadavers.

Neither medicine nor society is ready to include patients with cerebral death among potential transplant organ donors. From a medical, scientific, and ethical point of view, however, the only missing link is the documentation process. Often it is not possible to prove with 100 percent certainty that the vegetative state diagnosed is irreversible. This has to be researched.

Since cerebral death develops more slowly, one would have to wait for up to 1 month after a head injury and at least 1 to 2 weeks after cardiac arrest, before one can clinically determine the irreversibility of such a state.

Much research is needed (and should be funded by the National Institutes of Health) on the documentation of the irreversibility of cerebral death, and the methods which might be considered for organ removal from heart-beating and breathing cadavers. The time for including cerebral death victims among potential organ donors has not yet come.

In summary, first, organ transplantation should receive priority as one among many vital health care needs of the Nation.

Second, regional programs and legislation should facilitate procurement of organs to be matched with needs, more so than with perceived demands.

Third, plans should now be made for the time when the immune rejection problem will have been solved by ongoing research.

Fourth, one mechanism for increasing organ procurement is motivating physicians, particularly intensive care physicians.

Fifth, brain death certification should be enhanced by appropriate changes in reimbursement and hospital accreditation requirements.

Sixth, presumed consent, although desirable, shall first have public opinion consent by a poll.

Seventh, research into the preservation of donor organs should be fostered and funded.

Eighth, research into the cerebral death determination should be fostered and funded.

Thank you.

[The prepared statement and attachments of Dr. Safar follows:]

TESTIMONY BY PETER SAFAR, M.D., UNIVERSITY PROFESSOR AND DIRECTOR OF RESUSCITATION RESEARCH CENTER, UNIVERSITY OF PITTSBURGH

Testimony by Peter Safar
Hearings on Procurement and Distribution
of Human Organs for Transplantation
Subcommittee on Investigations and Oversight
Committee on Science and Technology
U.S. House of Representatives
April 27, 1983

INTRODUCTION

My name is Peter Safar. I am a physician, "Distinguished Service Professor of Resuscitation Medicine," and Director of the Resuscitation Research Center of the University of Pittsburgh. I am engaged almost fulltime in research on acute dying processes and their reversibility. Our research programs are in the laboratory, with patients, and in the community. I was the initiator and chairman of the Department of Anesthesiology and Critical Care Medicine at the University of Pittsburgh and before that, Chief Anesthesiologist at the Baltimore City Hospitals, where my associates and I developed America's first physician-staffed medical-surgical intensive care unit. In Pittsburgh, my associates and I started in 1963 the first critical care medicine physician fellowship training program, and in 1979 the western world's first multidisciplinary Resuscitation Research Center. I was founding member and president of the Society of Critical Care Medicine; and member of the White House Interagency Committee and the National Research Council Committee on Emergency Medical Services, the first American Heart Association Committee on Cardiopulmonary Resuscitation,* and other standard setting groups at state, national and international levels, concerning anesthesiology, resuscitation, emergency care and critical care (intensive care). My associates and I have been credited with the research which led to the teaching of mouth-to-mouth resuscitation, and co-initiated cardiopulmonary resuscitation and brain resuscitation. The latter includes studies of brain death and vegetative state.

In addition to my professional activities, I have personal experience with the occurrence of brain death and organ donation in my own family. In June 1966, my 12 year old daughter Elizabeth, a chronic asthmatic, asphyxiated to cardiac arrest, in her parents' absence. The heart was restarted but her brain remained dead. In order to add meaning to her life and death and to help change the then unsound practices of cadaver kidney transplantation, my wife and I gave permission (to my knowledge for the first time) for transplant surgeon Dr. Bernard Fisher to remove organs from my daughter's brain dead body, before the cessation of heart beat and the discontinuation of mechanical ventilation. Elizabeth's life and death obviously influenced my work in intensive care medicine and resuscitation research, as well as this testimony.

In 1968, coincident with the publication of the Harvard criteria for brain death certification, a local committee in Pittsburgh spelled out criteria and mechanisms for brain death determination. My associate, Dr. Ake Grenvik, Professor of Anesthesiology and Surgery and Director of Critical Care Medicine at the University of Pittsburgh, and I served on this committee. Soon thereafter, Dr. Grenvik was, to my knowledge, the first one to implement these procedures in the USA in an orderly fashion (see enclosures). His work on organ procurement in the intensive care units of the University Health Center of Pittsburgh, particularly at Presbyterian-University Hospital, for over 10 years, pioneered this field. His group has continuing experience not only with procurement of kidneys, but also with heart, lung, liver and pancreas transplantation. My associates and I have been advisors for the guidelines for the Determination of Death (JAMA 246:2184, 1981) and Management of the Permanently Unconscious Patient, which were recently developed by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. I also served recently on a panel of 10 physicians, who met in Boston under the auspices of the Society for the Right to Die, and who established guidelines for the management of hopeless, terminally ill patients, including the "letting die" of patients in persistant vegetative state (in preparation for publication).

Since I am not a transplant surgeon, I have no vested interests. My testimony will reflect my personal knowledge, attitudes and values, based on experiences with patient care, teaching, research, administration and program initiation in anesthesiology, resuscitation, emergency care and intensive care. My testimony is further influenced by my continuing professional relationships with my associate Dr. Grenvik (enclosures); Mr. Donald Denny, Director of Western Pennsylvania's organ procurement program; two transplant surgeons; and two forensic pathologists.

RECIPIENTS

For end stage renal failure, about 62,000 patients are presently on dialysis; about 5,000 patients received kidney transplants last year in the USA. Transplants are more cost effective than dialysis. In Sweden about 600 patients are on chronic renal dialysis while 500 received kidney transplants in one year. The difference between these two countries' ratios is attributed to our country's economic incentives for dialysis. This example demonstrates the importance of establishing true needs rather than merely reacting to demands. Since the introduction of cyclosporine for suppression of the immune rejection of transplanted organs in 1980, about 100 kidneys per year are transplanted at the Presbyterian-University Hospital in Pittsburgh, with an over 80% graft survival rate; 94% of the patients survived. Pittsburgh has also become a center for heart and liver transplantations. Until now, about 40 hearts have been transplanted, with about 65% short-term patient survival. Projected long-term graft survival is estimated as 50%. Two of the 4 heart-plus-lungs transplant recipients of Pittsburgh (and 6/12 at Stanford) are at home. In the past two years, 88 patients received liver transplants (some of them more than one), with 55% up to one year survivors. These data suggest that kidney transplantation, which has become an important part of general life saving medicine, may soon be followed by heart, liver and heart-lung transplantations, which are still to be considered innovative therapy, or research.

Once the immune rejection problem is solved, the need for multi-organ donors may increase to 50-100,000 per year in the USA. While about 50% of the 62,000 patients with end stage renal failure now on dialysis, i.e., 30,000, are estimated to be suitable recipients. The number of candidates for heart transplants may become even greater. Transplantations of hearts can be expected to mushroom once the operative mortality and rejection rate drops below about 20%. Most likely, artificial heart devices will prove to be effective more for temporary artificial circulation while the patient with a failing heart is evaluated as to the recuperability of his own heart, or is being considered for transplantation. Transplanted hearts seem to adapt better than presently available artificial hearts to changes in functional demands. Heart transplants already give a chance for return to a high quality of life.

While transplantation of kidneys should compete with other general health care priorities, transplantations of hearts, lungs and livers are still in the realm of experimentation, and therefore should be carried out in a few centers only, which are specially funded for coordinated multidisciplinary research. Transplantation surgery which becomes general medical care, such as kidney transplants, should receive public funding but with consideration of other still unmet health care needs nationwide. Setting priorities for expensive health care programs requires data and dialogue between the medical profession and the lay public. High priority must be given to cost effective preventive measures against life threatening illness or injury, and to programs which combat malnutrition, neonatal mortality, atherosclerosis, sudden cardiac death, infectious diseases and death and crippling from trauma. Resources are always finite. Costs should be measured in terms of years of survival gained. Assessment of benefits should include quality of survival.

DONORS

Because of the sensitivity of vital organs to a reduction in the supply of oxygen and nutrients, the transplantation of viable kidneys, hearts, lungs, livers, pancreases, etc., requires procurement of organs from brain dead cadavers with the heart kept beating by breathing machine. To meet the above mentioned need for 50-100,000 multi-organ donors per year in the near future, methods will have to be found to increase the procurement of organs suitable for transplantation. In recent years, organs were procured from only about 2500 brain dead donors per year in the USA. The estimated maximal number of brain dead donors presently available is about 20,000 per year in the U.S.A. This estimate is based on about 2% of the 1 million deaths which occur each year in our nation's hospitals (another 1 million deaths per year occur outside hospitals). At present only an estimated 5,000 patients received organ transplantations last year in the U.S.A. In 1981, 3,400 kidneys were transplanted, while 6,000 patients are on waiting lists. This figure should be higher considering the estimated 30,000 suitable candidates for kidney transplantation. Methods have to be devised to increase the number of donors and to make maximal use of available donor organs.

Present organ procurement. In most major medical centers with advanced intensive care units patients who develop brain death (e.g., from trauma, oxygen lack, stroke, tumor) are managed as recommended (see references). This includes a detailed orderly determination of brain death according to clearly spelled out criteria, certification of brain death by two physicians not of the transplant team, obtaining of consent from the next of kin to remove organs for transplantation, and finally operative removal of organs from the heart beating cadaver prior to discontinuing the ventilator. This safe and orderly process is not always followed in some community hospitals, as illustrated by an occasional patient in the past transferred to our hospital for organ transplantation, with the diagnosis of brain death, in whom the prescribed orderly examination revealed that he was not brain dead, and continued life support resulted in recovery. There also seem to be physicians who because of not wanting to be bothered or because of fear of malpractice suits, shy away from initiating brain death certification and rather let nature take its course. Most (but not all) brain dead patients on artificial ventilation develop intractable decrease in blood pressure and heart arrest occurs within 1 week while artificial breathing is continued. Such practice should be discouraged, since it not only deprives others of viable organs, but also adds unnecessarily to intensive care costs. Therefore, an educational campaign for health professionals is indicated.

Voluntary donation by family members has, in the experience of Grenvik's group at Pittsburgh, posed no major problems. The majority of families approached at the time of brain death certification have considered organ donation a positive act, to give the life and death of the deceased additional meaning. These positive feelings were seen in spite of shock and grief. Nevertheless, about 1 of 5 families of potential donors' approached by others have refused donation. Hesitancy on part of primary physicians to approach the family during shock and grief, when he the physician has a feeling of failure in the face of the patient's demise, understandably adds to a low organ procurement rate.

The carrying of donor cards has not been effective since "our own death is indeed unimaginable" (Freud) and people prefer not to plan for it. Education of physicians, particularly those controlling brain death certification in intensive care units, has been effective but should be intensified to include those responsible for the care of ICU patients in community hospitals. Financial incentives given by Medicare reimbursement schemes and requirements of hospital accreditation boards for orderly brain death determination would help in the procurement of a greater number of organs from brain dead potential donors in not only transplant hospitals, but the majority of hospitals nationwide. There should be increasing consideration given to the transfer of heart beating cadavers to transplantation hospitals for multiple organ procurement. This donor transfer is needed for heart and lung transplants, since the lungs must be transplanted within one hour. Transfer would have to be carried out by mobile ICU ambulances staffed with paramedics under physician direction--covered by health insurance.

Presumed consent for autopsy and organ donation. Historically, Emperor Joseph II of Austria in the 1700s established a law (which still prevails in Europe) which enables doctors to perform autopsies on patients who die in hospitals, to determine the cause of death and enhance scientific knowledge, without asking for consent. The patient's relatives, however, could refuse, which very rarely happened. This presumed consent for autopsy was used widely by European medical researchers since the mid-1800s for pioneering great advances in medicine. In my own efforts to improve emergency medical services in the U.S.A., I have frequently been frustrated by the inability to determine the cause of death and the potential salvagability of a victim of acute illness or injury. Autopsies are needed for quality control of care and for gaining new knowledge to advance the therapeutic potentials of medicine. In the U.S.A., only in cases of suspected mishaps or a wrong doing will the medical examiner or coroner get involved; only he may use implied consent for autopsy. In some states this includes implied permission to remove eyes or other organs from the cadaver. For transplantation, the general health of donors should be established by autopsy. The operation of organ removal in a way represents a partial autopsy while the heart is beating. Transplantation would benefit from at least giving medical examiners automatic permission to remove organs, and to delegate autopsies and organ removal to the hospital.

Presumed consent would probably be an effective mechanism to overcome inertia and increase organ procurement. It is possible that in the U.S.A. such presumed consent legislation would be declared unconstitutional. The presumed consent for autopsy has in recent years in some European countries been expanded to a presumed consent for organ donation. A recent review (Stuart, et al.) revealed that these countries include Austria, Czechoslovakia, Denmark, France, Israel, Poland and Switzerland. There is a trend that other European countries will follow, as presumed consent has been recommended by the European Committee on Legal Cooperation (equivalent to our National Conference on Uniform State Laws). In my opinion, automatic permission for hospital physicians to carry out autopsies and organ donation (unless the family objects) without having to solicit consent from the family, would facilitate measures which are in the public interest, would advance knowledge for improving life-saving measures, would permit use of donor organs to keep others alive, and would merely represent a generalization of the already existing regulations under which medical examiners and coroners function in this country. Because of the deeply rooted voluntarism in the U.S.A., however, before embarking on a promotion of presumed consent legislation, it may be wise to carry out an opinion poll to prevent a backlash, which could result in increased public refusal of organ donation.

Improved organ preservation. The present method used for preventing death of organs removed from heart beating cadavers during waiting for and transfer to an appropriately matched donor (who may not be in the same hospital) consists of once flushing the vessels of the organ with a cold plasma substitute solution, and then putting the organ into a solution containing ice, without further organ perfusion. This deep hypothermia without perfusion reportedly keeps kidneys "alive" for up to 24-48 hours, hearts up to 4-6 hours, and livers up to 6-8 hours. These time constraints have made most transplantation procedures emergency operations. Particularly for heart and liver transplants, for which large teams are required, this call for 24 hour coverage by special personnel, which is costly and draws personnel away from other more salvageable patients. Continued perfusion with cold plasma substitute of kidneys has extended the "alive" period up to about 72 hours. There is a 25% loss of donor organs, partly due to nonviability reached between removal and implantation. I do not understand why such a primitive method of organ preservation prevails, and only minimal research toward improving organ preservation has been initiated. Since the turn of this century, physiologists have kept hearts beating outside the body for hours, using perfusion techniques. If organs removed from heart beating cadavers could immediately be "plugged into" an effective (not yet developed) preservation system, which would keep them "alive" for up to 1 week, one could not only make use of perhaps 20% more organs than is now the case from presently available donors, but also reduce the cost and manpower drain away from other parts of medical care by changing these emergency operations into planned elective procedures, which can be carried out in a safer and less costly way during day hours. Also the matching of donor to recipient could be done more thoroughly and the transport of organs over greater distances would be feasible.

Therefore, I recommend facilitation of organ preservation research and its funding by the National Institutes of Health. This is closely related to resuscitation research, which includes preserving the whole body and returning the whole organism from total circulatory arrest by reperfusion-reoxygenation, to viability of vital organ systems. For the preservation of transplant organs the questions to be pursued include: What are the limits of circulatory arrest time tolerated by each organ system, with and without reperfusion? While reduced temperature decreases metabolism and thereby protects against lack of oxygen and nutrient supply, the optimal low temperature which gives greatest reduction in metabolism and least tissue damage remains to be determined. What are the low limits of temperature tolerated in terms of hypothermia-induced tissue damage, using various perfusion fluids? What is the best perfusion fluid (plasma substitute vs. oxygen carrier, vs. blood), perfusion pressure and pattern (pulsatile vs. non-pulsatile flow), and temperature for preservation? What are the best methods for rewarming and reoxygenation? Should rewarming be done before implantation? What treatments should be part of reperfusion to sustain optimal viability of organs? There are various drugs and microcirculation promoting measures now being studied in our Center and others, for brain protection before and brain resuscitation after circulatory arrest, which may be suitable for organ preservation. While simple methods exist for efficient delivery of oxygen and removal of carbon dioxide, what would be the most cost-effective method for removal of metabolic by-products? These and other questions would have to be pursued separately for each organ. Of course, organ preservation would be greatly facilitated if multiple organ transplantations were to be carried out in only a few centers and multiple organ donors' heart beating cadavers were transferred with artificial ventilation to these centers.

Cerebral death. At present only corneae of eyes, bones, vessels and other organs with low metabolism are successfully transplanted after removal from non-heart beating cadavers at autopsy. Kidney, heart, liver and lungs must be taken from heart beating cadavers with brain death, and reach, via some preservation method, the recipient. Brain death, which can be determined with 100% certainty by a special combination of clinical and laboratory methods, equals "death" in medical and legal definitions. Brain death implies no spontaneous breathing, as it represents irreversible destruction of the entire brain, including the high thinking areas and the lower mid-brain and brain stem areas for vegetative existence. Brain death implies no spontaneous breathing.

Following injury or prolonged oxygen lack (as in heart arrest followed by resuscitation), many patients develop "cerebral death", not death of the entire brain. Cerebral death is irreversible destruction of the "cerebrum", with continued viability and activity of the mid-brain, cerebellum and medulla. These patients may breathe spontaneously, do not show some other signs of brain death (such as absent cranial nerve reflexes), but also are unresponsive and have no chance to recover human mentation. Cerebral death has also been named persistent vegetative state, apallic syndrome, or social death. Biomedical ethics in my opinion should not only equate brain death, but also cerebral death with "death". This would make a patient like Karen Quinlan, who is in such a persistent vegetative state, a "breathing and heart beating cadaver". Neither medicine nor society is ready to include patients with cerebral death among potential transplantation organ donors. From a medical-scientific and ethical point of view, however, the only missing link is the documentation, with 100% certainty, that the vegetative state diagnosed is irreversible. Such proof exists when with special methods one finds no blood flow through the cerebrum, when oxygen uptake is greatly reduced (difficult to measure), or when CAT x-ray examination shows severe atrophy of the cerebrum. Research in our and others' laboratories also is presently searching for chemical measurements with which one might prove early after an insult, the irreversible destruction of the higher centers of the brain in the absence of brain death. Since cerebral death develops more slowly, one would have to wait for up to about 1 month after head injury and at least 1-2 weeks after heart arrest, before one can clinically determine the irreversibility of this state. Much research is needed, and should be funded by the National Institutes of Health, on the documentation of the irreversibility of cerebral death (without total brain death), and on methods which might be considered for organ removal from heart beating and breathing cadavers. Therefore, the time for including cerebral death victims among potential organ donors has not yet come.

RECOMMENDATIONS

1. Organ transplantations should receive priorities from national, regional and institutional planning groups, as one among many vital health care needs of the nation, and in consideration of available finite resources, quality of survival and alternative therapies. Competing priorities include programs to combat malnutrition, infectious diseases, neonatal mortality, atherosclerosis, sudden cardiac death, and death and crippling from trauma.

2. As soon as a specific organ's transplantation procedure has emerged from the stage of research and is considered part of general life saving medical care (e.g., kidney transplantation), regional programs and legislations should facilitate procurement of organs to be matched with needs.

3. Since presently many more donor organs (kidneys, hearts, livers) are needed than are donated, procurement must be increased. Plans should now be made for the time when the immune rejection problem will have been solved by ongoing research, and the public will demand a massive increase in procurement.

4. Possible mechanisms for increasing organ procurement now include the motivating of physicians (particularly critical care medicine-intensive care unit physicians, emergency physicians, neurosurgeons and neurologists) to identify all potential organ donors and to initiate transfer, brain death determination and certification, obtaining of consent, removal and preservation of viable organs, and matching with the most appropriate recipients--all in an orderly manner with the collaboration of organ procurement-transplant agencies at the regional and national levels.

5. Orderly brain death certification and interhospital transfer of organs or heart beating brain dead donors should be enhanced by appropriate changes in Medicare reimbursement and in hospital accreditation requirements by state governments and the Joint Commission on Accreditation of Hospitals.

6. Another mechanism for increasing organ procurement would be legislation for "presumed consent" for autopsies and organ removal for transplantation, as it exists in several European countries. Although desirable, efforts toward such presumed consent legislation might cause a backlash. Therefore, an opinion poll should be conducted before promoting such legislation.

7. Research into improved and prolonged preservation of donor organs should be fostered and funded by the National Institutes of Health. Improved organ preservation is badly needed, not only for the better utilization and retention of available organs, but also for making transplant operations elective, and thereby safer and less expensive than present emergency transplant operations. The not entirely utopian goal would be organ banks not only for corneae, bones, etc., but also for kidneys, hearts, lungs, livers and other vital organs.

8. Research into "cerebral death" determination should be fostered and funded by the National Institutes of Health. At present, the only sources of donor kidneys, hearts, lungs and livers are heart beating cadavers with brain death. In the future, additional sources could be heart beating and breathing cadavers with cerebral death. In brain death, the entire brain is destroyed (higher and lower centers). In cerebral death, the higher centers only are destroyed, which results in permanent loss of human mentation and unconsciousness (persistent vegetative state, neocortical death, apallic syndrome, social death). Once cerebral death can be determined with 100% reliability (as is now the case for brain death), it should also be equated with "death." This would call for "letting die" for socio-economic and ethical reasons, which in turn would permit organ donation. Much research, however, is still needed before establishment of appropriate methods for reliable determination of cerebral death and methods for subsequent organ removal.

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Cessation of therapy in terminal illness and brain death

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Extracorporeal oxygenation may be considered in relatively young patients with severe respiratory failure and inadequate pulmonary gas exchange despite sophisticated mechanical ventilation. Similarly, when a failing heart does not respond to conventional medical and surgical treatment, it is appropriate to consider augmented circulation by intraaortic balloon pumping or left ventricular assist devices, or even cardiac transplantation. However, for patients with irreversible failure of multiple organ systems, terminal neoplasia, or complete and irreversible brain failure, medical, philosophical, moral, financial, and theological considerations may dictate limitation or removal of those diagnostic and therapeutic measures which have been judged inappropriate. But until reliable criteria for predicting irreversible severe brain damage become available, physicians must continue to use highly individualized judgment based on a combination of the medical team's clinical experiences, published data, and outcome prediction indices, as well as the patient's own wishes, stated while still conscious and mentally competent. This has created a significant dilemma for most physicians, best illustrated by the famous Karen Ann Quinlan case in New Jersey, where the Supreme Court requested that the hospital establish an "Ethics Committee" to make these decisions regarding withdrawal of therapy, as has previously been done at Massachusetts General Hospital in Boston.[1]

A TRIAGE PROGRAM FOR CRITICAL CARE

Since modern technological advances have given today's physicians the ability to prolong life in critically ill patients even when cure is no longer possible and a final cardiac arrest is inevitable, physician control over the time and mode of dying has greatly increased. Consequently, controversy has arisen over unwarranted cardiopulmonary resuscitation (CPR) and continued life support in certain situations.[2, 3] In fact, if an agreement has been reached with the patient or his relatives not to perform resuscitation, such therapy would be a violation of that patient's right to determine his own care.[8] The terms "Do Not Resuscitate", "DNR" or "No Code" have commonly been applied to such patients. In our experience, however, these terms are very confusing since they have been interpreted to mean anything from complete withdrawal of all therapy to aggressive support of the patient with the exception of CPR.

To define more closely those aspects of care considered appropriate within each patient's total care plan, Presbyterian University Hospital implemented "Guidelines for the Care of Hopeless/Moribund Patients" in 1975. These guidelines separate the "Do Not Resuscitate" patients into two categories: "All But CPR" and "No Extraordinary Measures". Together with previously designed guidelines for the evaluation and certification of death based on "Brain Death",[4] to be discussed below, the new guidelines permit distinct categorization of all ICU patients into four different groups: "Total Support", "All But CPR", "No Extraordinary Measures", and "Brain Death" (Table 1). It should be noted that the condition and prognosis of the patient's brain is of great importance for selecting the appropriate category, since the function of many of the other vital organs in the body can be artificially supported.

Following ICU admission, all patients are categorized as and receive "Total Support" until a thorough data base has been obtained concerning diagnosis, organ system involvement, likely prognosis, etc. Simultaneously, any potentially reversible aspects of the patient's illness are aggressively treated. After consul-

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TABLE 1. CCM triage program, Presbyterian University Hospital, Pittsburgh, PA

1. *Total support:* all patients are assumed to be in this category on ICU admission. Critically ill or injured patients in whom survival without persistent severe brain failure is expected, remain in this category. Vital organ systems, although usually affected, are not irreversibly damaged. In these patients, everything possible is done to reduce mortality and morbidity.

2. *All but CPR:* these are patients with continuing brain function or at least hope for some meaningful brain recovery and who have irreversible cardiopulmonary or other multiple vital organ failure, or are in the terminal stages of other incurable diseases, e.g., advanced carcinomatosis. Every indicated therapeutic approach is utilized in these patients but only to the point of cardiac arrest. When this occurs, CPR is not provided and the patient is permitted to die.

3. *No extraordinary measures:* these are patients where some forms of treatment seem meaningless, prolonging death rather than life; examples are patients with minimal brain function without hope for improvement and thus no prospect for future human mentation. In these cases, extraordinary measures, such as defined below and within the patient record, are usually not initiated, and are discontinued if such discontinuation is not expected to result in immediate demise. Obviously, these patients will not be resuscitated in case of cardiac arrest. In addition to CPR, extraordinary measures which may be withheld include: admission to the ICU; arrhythmia control; tracheal intubation; life support with mechanical ventilation and other assisting devices; use of artificial organs; transplantation of organs and tissues, including blood and blood by-products; invasive monitoring; parenteral nutrition; and iv infusion of potent vasoactive drugs.

4. *Brain death:* patients with irreversible cessation of all brain function are placed in this category. Once brain death has been demonstrated by established criteria, the patient is declared dead and all therapy is stopped. However, if organ donation for transplantation is being considered, cardiopulmonary support is continued until the required organs have been removed.

tation with the Critical Care Medicine (CCM) physician and involved consultants, the attending physician or his designate reviews the patient's classification at least daily and may recategorize at any time. All such decisions are discussed with the patient's family and the wish of the mentally competent patient is also always considered.

A progress note which identifies the reasons for the categorization and includes information that a discussion with the patient or the patient's family has taken place and that all parties agree must be entered in the medical record by the attending physician or his designate. Likewise, an order is placed in the medical record identifying the patient's category and defining what therapy is considered appropriate or inappropriate in the patient's care, e.g., intubation and mechanical ventilation, treatment of dysrhythmias, etc. This careful documentation of decision-making provides the necessary communication to other physician consultants, nurses, and paramedical personnel as to what treatment forms should or should not be anticipated. Thus, the initiation of therapy which has been excluded from the patient's care plan, e.g., CPR, or the omission of an appropriate treatment is less likely to occur. In the absence of an order identifying a specific patient category, total support is always provided.

Our experiences with the new CCM Triage Program were analyzed for the first two years following its implementation. During July 1975 through June 1977, there were 1752 patients admitted to the ICU (Table 2). Patients who remained in the "Total Support" category comprised 81.3% of the total admissions and sustained an ICU mortality rate of 7.9%. The "All But CPR" classification of 105 patients or 6.0% of all admissions had an ICU mortality rate of 80.0% as compared to 86.6% among the 142 patients categorized as "No Extraordinary Measures", constituting 8.1% of the admissions. Eighty patients were discharged within the "Brain Death" category, accounting for 4.6% of the total ICU admissions. By definition, brain dead patients had 100% mortality.

Of particular interest are those patients for whom the designated treatment plan in their categories "All But CPR" and "No Extraordinary Measures", resulted in survival with transfer of the patients from the ICU and the hospital (Table 3). Our results indicate that the positive aspects of treatment must be emphasized in these patients also. In both categories, extensive treatment plans should be utilized, once the proper role of each component has been defined within the context of the probable prognosis of the overall disease process. Therefore, the classification guidelines best serve to stimulate and crystallize decision-making as to what is the appropriate positive extent of therapy, before excessive emotional, financial, and medical burdens are incurred by the patient, family, and staff. As a communications system, these guidelines serve to reassure family, staff and at times, also the patient, that the inappropriate psychological and/or physical discomfort or pain will be avoided.

Other systems have been described[1-6] for patient categorization and share as a goal the effort to lessen unnecessary prolongation of death while providing an appropriate level of support to patients with some possibility of surviving and regaining at least basic

TABLE 2. CCM triage program, Presbyterian University Hospital, Pittsburgh, PA. Distribution and ICU mortality within patient categories 7/1/75–6/30/77

Category	Patients	Deaths	%
Total support	1425	112	7.9
All but CPR	105	84	80.0
No extraordinary measures	142	123	86.6
Brain death	80	80	100.0
Total	1752	399	22.8

TABLE 3. CCM triage program, Presbyterian University Hospital, Pittsburgh, PA, 7/1/75–6/30/77. Patients discharged alive from the ICU categorized "All But CPR" or "No Extraordinary Measures"

Category	All but CPR	No extraordinary measures
	(n = 105)	(n = 142)
Died elsewhere in hospital	12 (11.4%)	11 (7.8%)
Transferred to chronic care institution	5 (4.8%)	5 (3.5%)
Discharged home	4 (3.8%)	3 (2.1%)
Total no. of patients discharged alive from ICU	21 (20.0%)	19 (13.4%)

levels of vital organ function, which includes brain function.

BRAIN DEATH DETERMINATION

In those circumstances where no chance of meaningful recovery of sapient function is possible because all the brain itself has been functionally destroyed, a process for certification of that state becomes necessary.[7] Traditionally, within both the medical and legal professions, death of the patient has been equated with irreversible cessation of respiratory and cardiovascular function. During the 1970's legislative attempts have been made to define a second type of death, i.e., brain death, based upon irreversible cessation of all brain function. Regardless of the sequence of events leading to this outcome, there is, however, only one meaningful death event, i.e., death of the brain. Thus, irreversible cardiac arrest, which can be treated by insertion of an artificial heart or cardiac transplantation, leads to death of the individual only when brain function ceases.

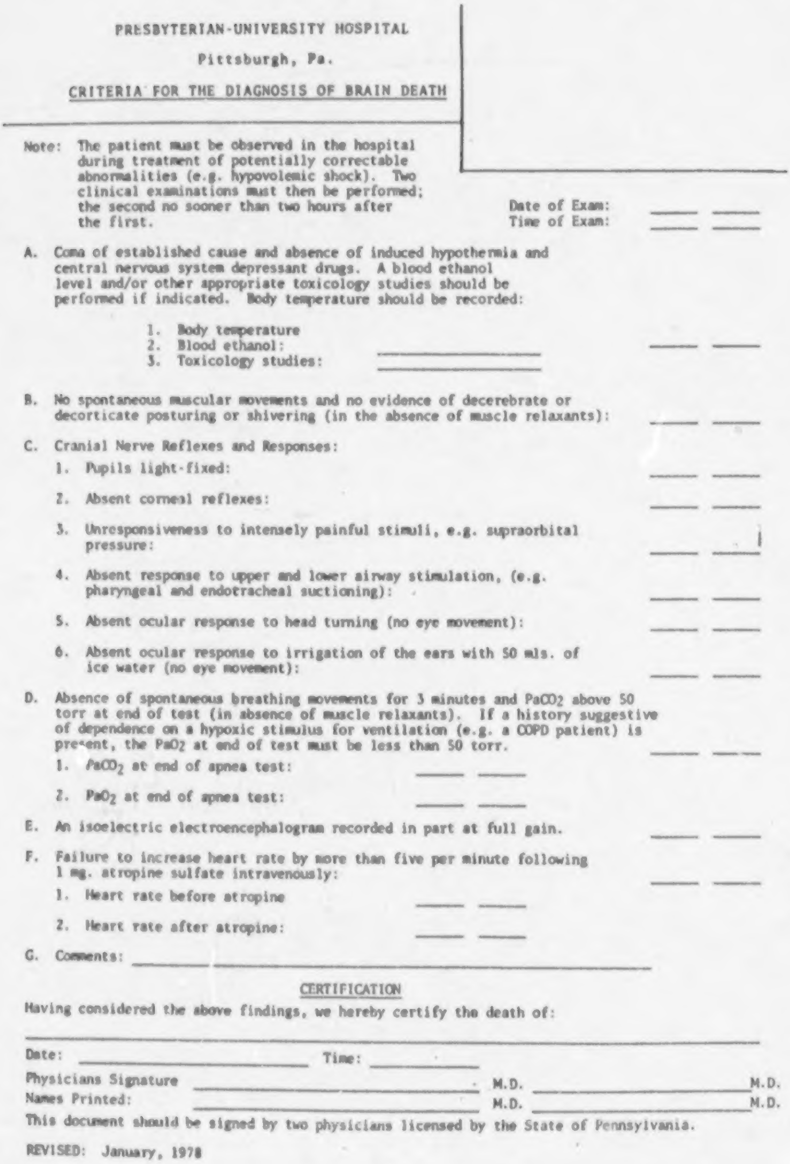
As clinically defined, brain death identifies a permanent loss of all integrated neuronal brain function.[8, 9] The term "integrated" is important to the definition, since recovery of some metabolic and electrical activity in the brain following even 60 min of total ischemia has been demonstrated experimentally.[10] It is also important to realize that there is a difference between cerebral death and brain death, the former permitting survival of parts or all of the brain stem, pons, midbrain, and cerebellum, while the latter indicates death of all brain structures above the foramen magnum. So far, only brain death has been medically and legally equated with death of the individual.

Cardiac arrest usually occurs within 72 hours[11-14] in the majority of brain dead patients supported by mechanical ventilation. However, to our best knowledge, the longest surviving body of a brain-dead patient was a young male treated for 36 days in an ICU; medical documentation of brain death was performed repeatedly, including clinical evaluation plus carotid and vertebral arteriography showing no evidence of any blood supply to the brain (Holmdahl, personal communication). Obviously, such intensive therapy, if generally applied, would effectively drain our medical and economical resources. Once there is medical/scientific proof that all brain function has irreversibly ceased, ethical and religious viewpoints,[15, 16] both by professional authorities and the lay public, justify death certification and cessation of all treatment, now also accepted by the legal community as the only logical approach.[17-20]

Specific criteria for determining brain death have originated from many different groups including: Harvard Medical School,[7] University of Pittsburgh,[21] University of Minnesota,[22] University of Pennsylvania,[23] United States Navy,[24] Medical Colleges of the United Kingdom,[25, 26] National Institutes of Health Collaborative Study on Cerebral Survival,[9] and others.[27-30] While the many guidelines differ regarding individual tests recommended, all require a detailed careful neurologic examination and most include EEG. Repeat evaluations may or may not be demanded. Reexamination after specified time intervals has been recommended. These intervals include: 24 hours,[7] 6 to 12 hours,[14, 23, 24, 31] 2 to 3 hours,[4, 21, 32] 30 min,[22] or variable time periods depending upon etiology.[26] Certification of brain death after a single examination in patients with known and irreversible cause for complete brain dysfunction has also been supported.[8, 12, 25, 27, 30]

The so-called persistent vegetative states,[33, 34] with severe neurological dysfunction yet some persisting brain activity, are a separate ethical and medical issue. These conditions must be actively sought and excluded from the brain-dead patient population. They can generally be subdivided into: (1) "locked-in" syndromes (akinetic mutism, paralytic akinesia, cerebromedullospinal disconnection), wherein some mental awareness may be preserved and significant cranial nerve dysfunction exists but voluntary muscle movements are absent,[35-37] e.g., medullo-pontine lesions; (2) clinical states characterized by profoundly depressed levels of awareness with associated EEG depression even to an isoelectric level but with brain stem function which continues or can be evoked,[38-48] sometimes is also referred to as the apallic syndrome.[49]

It is obvious from the above that both cortical and brain stem functions must be cautiously examined by any criteria adopted for determination of brain death. A well defined set of criteria was developed in Pittsburgh in 1969 by a committee of clinicians, lawyers, philosophers and clergymen[21] and was implemented the same year[4] in the ICU at Presbyterian University Hospital. These criteria have been modified in 1978 to its present form (Fig. 1). During 1970 through 1976, 176 consecutive cases developing brain death were certified dead based on the original criteria (Table 4). These did not include the need for hospital observation prior to brain death certification, the atropine



PRESBYTERIAN-UNIVERSITY HOSPITAL

Pittsburgh, Pa.

CRITERIA FOR THE DIAGNOSIS OF BRAIN DEATH

Note: The patient must be observed in the hospital during treatment of potentially correctable abnormalities (e.g. hypovolemic shock). Two clinical examinations must then be performed; the second no sooner than two hours after the first.

Date of Exam: ____ ____
Time of Exam: ____ ____

A. Coma of established cause and absence of induced hypothermia and central nervous system depressant drugs. A blood ethanol level and/or other appropriate toxicology studies should be performed if indicated. Body temperature should be recorded:

1. Body temperature
2. Blood ethanol: ____________ ____ ____
3. Toxicology studies: ____________

B. No spontaneous muscular movements and no evidence of decerebrate or decorticate posturing or shivering (in the absence of muscle relaxants): ____ ____

C. Cranial Nerve Reflexes and Responses:

1. Pupils light-fixed: ____ ____
2. Absent corneal reflexes: ____ ____
3. Unresponsiveness to intensely painful stimuli, e.g. supraorbital pressure: ____ ____
4. Absent response to upper and lower airway stimulation, (e.g. pharyngeal and endotracheal suctioning): ____ ____
5. Absent ocular response to head turning (no eye movement): ____ ____
6. Absent ocular response to irrigation of the ears with 50 mls. of ice water (no eye movement): ____ ____

D. Absence of spontaneous breathing movements for 3 minutes and $PaCO_2$ above 50 torr at end of test (in absence of muscle relaxants). If a history suggestive of dependence on a hypoxic stimulus for ventilation (e.g. a COPD patient) is present, the PaO_2 at end of test must be less than 50 torr. ____ ____

1. $PaCO_2$ at end of apnea test: ____ ____
2. PaO_2 at end of apnea test: ____ ____

E. An isoelectric electroencephalogram recorded in part at full gain. ____ ____

F. Failure to increase heart rate by more than five per minute following 1 mg. atropine sulfate intravenously: ____ ____

1. Heart rate before atropine ____ ____
2. Heart rate after atropine: ____ ____

G. Comments: ______________________

CERTIFICATION

Having considered the above findings, we hereby certify the death of:

____

Date: ____________ Time: ________
Physicians Signature ____________ M.D. ____________ M.D.
Names Printed: ____________ M.D. ____________ M.D.

This document should be signed by two physicians licensed by the State of Pennsylvania.

REVISED: January, 1978

FIG. 1.

TABLE 4. Patients certified brain dead 1970–1976 Presbyterian University Hospital, Pittsburgh, PA

Etiology	No. (%)	Age	
		Range	Mean
Cerebral bleeding	70 (39.8)	18–76	44
Trauma	58 (32.9)	11–65	30
Postresuscitation	20 (11.4)	17–89	48
Vascular occlusion	14 (8.0)	18–76	44
Tumor	6 (3.4)	22–62	48
Miscellaneous	8 (4.5)	16–54	43
Total	176 (100.0)	11–89	41

test, and the hypoxemia test in COPD patients but were otherwise identical to those shown in Figure 1.

The etiologies responsible for brain death and other characteristics of this patient group are summarized in Table 4. In all patients, therapy with total life support techniques was continued during diagnostic evaluations directed toward identification of a reversible etiology of the depressed brain function. If toxic, metabolic, pharmacological, infectious, or any other potentially reversible cause of coma could be defined, appropriate therapy was continued and the brain death certification process suspended. Different forms of shock, if present, will aggravate any coexisting cerebral dysfunction, e.g., in multiple injury[4] and must, therefore, be vigorously treated before brain death evaluation takes place.[9]

Our criteria for brain death include complete absence of cerebral and brain stem activity on two clinical examinations, performed at least 2 hours apart and a single isoelectric EEG which is recorded using standardized technical guidelines to ensure maximal sensitivity,[50] i.e., recording with and without auditory stimulation for at least 30 min, part of which must be with an amplification of two microvolts per mm. The EEG is usually obtained during the interval between the first and second clinical examinations. Neuromuscular blockade with succinylcholine, pancuronium, or curare may be used to abolish muscle artifacts which interfere with the EEG tracing, but the effects of these agents must be absent before the subsequent clinical examination. This can easily be tested with an electric nerve stimulator, routinely used in anesthesiology for monitoring of the effects of such muscle relaxants.

A standardized neurological examination of cranial nerve activity and a three minute apnea test to detect signs of spontaneous breathing activity comprise the clinical phase of the evaluation. It is mandatory that brain stem, and not spinal cord activity, be investigated in the diagnosis of brain death, as spinal cord neurons may remain viable after brain function has ceased. Somatic motor movements from persistent spinal reflex activity were seen in 10.8% of our patients,[4] in agreement with the 9% incidence reported by others.[12] Occasionally, complex movement patterns may be seen, caused by spinal cord reflexes.[4,9] In these cases, simultaneous recording of the EEG during such movements provides assistance in excluding their origin in the brain.

Several hazards may be associated with the test for apnea. Because hypocarbia may induce apnea,[51] the Pa_{CO_2} should be normal at the start of the test. However, we have observed dramatic increases in intracranial pressure when the Pa_{CO_2} was allowed to rise to normal levels for an apnea test. This demonstrates the potential for further compromise of brain function during this test. Likewise, the patient should not become hypoxemic during the test. Therefore, it is required that before initiation of the apnea test, all other criteria of brain death be met, no effect of neuromuscular blocking agents be present, the patient be well oxygenated and the Pa_{CO_2} normalized.[52] After arterial blood gas analysis confirms this, the patient is disconnected from the ventilator and closely observed for 3 min. If no respiratory efforts are detected after 3 min, a second set of arterial blood gases is obtained and the patient reconnected to the ventilator. The apnea test is considered valid only if Pa_{CO_2} is well above normal range after 3 min of apnea. This indicates absence of ventilatory response to hypercarbia. If the patient's history suggests a dependence upon hypoxic drive for ventilation, the apnea test is conducted at that level of oxygenation.

When a patient fulfills the above criteria for brain death, he is certified dead by two licensed physicians. Because certification of death is the legal duty of the attending physician and although the relatives are always carefully informed about the various ramifications of brain death, the family's permission is not a required part of this procedure. The time of death is the time of brain death certification and *not* the time of cessation of cardiac activity. After the family has been informed of the death, mechanical ventilation is discontinued and the body kept in the ICU until cardiac activity ceases. If organ removal for transplantation purposes is to be performed, such brain-dead organ donors receive continued cardiopulmonary support until the donated organs are removed in the operating room. As soon as this has been completed, all cardiopulmonary support is discontinued and the body kept in the operating room until cardiac activity stops.

Management of brain-dead organ donors may at times be difficult. Cardiovascular instability, defined as a systolic arterial pressure of less than 100 mm Hg for more than 1 hour or the presence of a potentially fatal arrhythmia, occurred in 45% of our patients.[4] It is important that these possibilities be excluded as a potentiating cause of brain dysfunction via hypoperfusion prior to certification of brain death. Also, fluids, inotropic drugs, and other support of the cardiovascular system in the brain-dead patient may be necessary to preserve donor organ viability.

A wide variety of arrhythmias was encountered in our patient group. Although most responded to conventional therapy, it is important to realize that bradyarrhythmias will not respond to atropine, because their etiology is not that of increased vagal activity. In fact, an increased heart rate after atropine in a presumed brain-dead patient negates the diagnosis, as the atropine test is a sensitive indicator of brain stem function.[27]

Diabetes insipidus as a manifestation of absent hypothalamic function occurred in 8.5% of our patients[4] and necessitated careful fluid and electrolyte management.

DISCUSSION

The described method of CCM triage appears to be a useful system for any hospital. It is likely to be strengthened in the future when and if objective and reliable prognostic indicators of severe irreversible brain damage become available, in addition to those already proposed for other serious conditions.[53-56]

The participation of family members within our triage program is an absolute necessity for continuity of the patient-family-physician relationship through communication and education. Hesitation on the family's part is met with additional sensitive discussions and, when indicated, continued education concerning the patient's condition and the implications of changes in his or her status.

We have also seen cases in which relatives have requested withdrawal of treatment when the involved physicians considered the patient to have a sufficient chance of survival to warrant continued life support. In one drastic example, both the referring physicians and the relatives were led to believe that the patient had already succumbed due to irreversible cessation of all brain function. This was an 18-year-old man, admitted to our ICU with multiple injuries including brain contusion following a severe automobile accident. He was referred from another hospital for the sole purpose of kidney donation with consent forms for removal of these organs already signed by the parents. However, since the patient was in hypovolemic shock and did not meet our brain death criteria, total support was provided. He responded well to vigorous treatment of his hypovolemia and was discharged from the hospital after 2 months with his only residual neurological deficit being a right hemiparesis and slight impairment of higher cognitive functions.[4] Thus, the flexibility of this categorization system serves to reinforce the privileges of the medical profession in exercising their therapeutic prerogatives.

Patient categorization may be influenced but should not be automatically dictated by non-medical factors, such as those patients who may have declared an intention to "die with dignity" by means of a prepared statement, in writing or orally at some point before or during their hospitalization; in situations involving patients whose organs may be obtained at their death for transplantation into other patients; and those patients who may have declared an intention to donate their whole body or parts of it to science.

To emphasize the patient's right to refuse treatment, a legalized "living will" has been established in several states of the nation. This means that a physician following the instructions given by the patient cannot be legally accused of negligence when withdrawing or withholding treatment, if the patient's instructions to do so are clearly indicated in his living will. However, the cause of the patient's condition must be that which he had in mind when signing his living will, such as widespread cancer, and not a different medical problem which might be relatively easily correctable.

Traditionally, physicians in communication with the patient or the next of kin have decided on indicated therapeutic approaches. Our system does not deviate from this concept, only organizes this physician-patient-family relationship and decision-making, to avoid confusion and to emphasize that therapy deemed appropriate is, indeed, provided.

In this context, we are concerned with the recent decision of the Supreme Judicial Court in Massachusetts in the Saikowicz case,[57-59] indicating that decisions regarding withdrawal of treatment in any mentally incompetent or comatose patient *must* be done by court order and not by the attending physician. This not only reflects distrust of the medical profession but also introduces a cumbersome, unmanageable, expensive mechanism of triage in patient care.

The cost versus the quality of survival for ICU patients is an often discussed tangential issue.[60] We feel that continuing therapy, utilizing all forms of modern biomedical technology in patients who in the best considered medical opinion have no chance of survival with human mentation, is medically, ethically and economically unsound. Our system to identify patients in whom maximal expenditure of medical, emotional and manpower resources is inappropriate, has the potential for considerable financial saving to the society at large, estimated at 1 to 2 billion dollars per year in the United States alone. These resources may then be redirected toward patients whose prognoses are more favorable. Hence, this effort of patient categorization is not only to reduce the amount of inappropriate care, but also to increase the availability of care to those for whom that care is appropriate.

CONCLUSIONS

The following advantages of a triage program for critical care medicine have been identified:

1. It is a practical plan for management of all ICU patients.
2. It allows maximal efforts towards viable patients.
3. It provides a more humane ICU environment for

all involved (patients, relatives, physicians, nurses, and other ICU personnel).

4. It offers improved morale among ICU personnel.
5. It reduces overall expenses.

The disadvantages may include occasional misinterpretations of criteria. This necessitates careful supervision of the system at all times by individuals familiar with the program.

SUMMARY

Modern technological advances have given today's physicians the ability to prolong life in critically ill patients even when cure is no longer possible. Consequently, controversy has arisen over unwarranted continued life support in these situations. Fear of lawsuits in recent years has added to the confusion. Therefore, guidelines were developed at Presbyterian University Hospital in Pittsburgh which make it possible to categorize each ICU patient into one of the four categories: "Total Support", "All But Cardiopulmonary Resuscitation", "No Extraordinary Measures", and "Brain Death". Implementation of this categorization has proven to be a practical plan for management of all ICU patients. It allows maximal efforts towards viable patients, provides a more humane ICU environment for all involved, offers improved morale among ICU personnel and reduces expenses. However, the system necessitates careful supervision by a physician familiar with it.

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ERRATA

The following change should be made in the article entitled "A method of maintaining sterility of heated humidifiers in mechanical ventilator breathing circuits" by Robert S. Deane, MB, Bch, et al., published in the January–February 1978 issue of CRITICAL CARE MEDICINE. On page 61, line 9, following J. H. Emerson Co., Cambridge, MA) the following should be inserted "A-G. A 9 inch long, ¾ inch diameter copper pipe"....

The following change should be made in the article entitled "Pentobarbital therapy for intracranial hypertension in metabolic coma. Reye's syndrome" by Lawrence F. Marshall, MD, et al., published in the January–February 1978 issue of CRITICAL CARE MEDICINE. On page 3, line 11 the dosage of mannitol should be: (0.125 gl/kg dose).

As a result of the number of printer's errors in the article entitled "Cardiorespiratory and metabolic effects of profound hypothermia" by Omar Prakash, MD, et al., published in the May–June issue of CRITICAL CARE MEDICINE it will be reprinted in its entirety in the September–October issue.

The editor regrets any confusion caused to the readers as a result of these errors.

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In, Organ Procurement (Kootstra G, editor).

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MULTIPLE ORGAN PROCUREMENT BY INTERHOSPITAL TRANSFER OF HEARTBEATING CADAVERS

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When brain death develops in serious illness or severe head injury, cardiac arrest usually occurs within 72 hours in patients supported by mechanical ventilation (1-4). It is during this brief period of time that organ donation can be considered. The concept of brain death has changed little since the publication of the original Harvard criteria in 1968. However, legislation in this field has been slow and to date eleven states still lack legal identification of death which includes brain death. Therefore, the American Guidelines for the Determination of Death, published by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (5), were particularly welcome by transplantation centers, since up to date standards were established which clarified certain problems in the Harvard criteria (6). These guidelines by the President's Commission require documentation that: 1) cerebral and brainstem functions are absent; 2) this condition is irreversible which necessitates known cause of the condition and exclusion of the possibility of recovery; and 3) the cessation of all brain functions persists for an appropriate period of observation and/or trial of therapy.

To avoid confusion between brain death and the so-called persistent vegetative states (7), the President's Commission Guidelines (5) also advise that the criteria physicians use in determining that death has occurred should: 1) eliminate errors in classifying a living individual as dead; 2) allow as few errors as possible in classifying a dead body as alive; 3) allow a determination to be made without unreasonable delay; 4) be adaptable to a variety of clinical situations; and 5) be explicit and accessible to verification.

The criteria for brain death used at Presbyterian-University Hospital (PUH) in Pittsburgh (see Appendix) include complete absence of cerebral and brainstem activity on two clinical examinations, performed at least two hours apart, plus a single, maximally sensitive, isoelectric EEG (8). This EEG must be recorded with and without auditory stimulation for a minimum of 30 minutes and at least part of the test must use an amplification factor of two microvolts per millimeter. The clinical part of the evaluation is a standardized neurological examination of cranial nerve activity and an appropriate apnea test to detect signs of spontaneous breathing. If there is any sign of brain function during either clinical examination, death cannot be certified.

The most recent problem encountered in brain death certification is the transport delay caused by conflicting criteria among hospitals transferring dead patients for multiple organ harvest and transplantation (9). For transplantation of hearts, kidneys or livers, donor organs may be retrieved at a distance from the transplant center. Kidneys are kept viable in hypothermia with specially designed perfusion machines. Hearts and livers are chilled by perfusion of hyperosmolar solutions at +4°C and transported cold, sometimes thousands of miles by charter or private jet air craft. While ischemia time is variably prolonged, risks to donor organs are generally acceptable. However, in combined transplantation of heart and lungs, the lungs are more prone to ischemic injury. For such transplantation, ischemia time is minimized by procuring these organs at the transplant center.

When a brain dead donor with a beating heart is transferred from another hospital to PUH for the purpose of harvesting multiple organs, the body arrives with full cardiopulmonary support including mechanical ventilation, continuous infusion of IV fluids and electrolytes, EKG and pressure monitoring, etc., for optimal preservation of extracranial organs. The donor has already been certified dead at the referring hospital based on brain death criteria. Consent has already been obtained from the next-of-kin and coroner as indicated for organ removal.

The body is not admitted to a specific PUH physician but the cardiac transplantation group is responsible for management of the body and the medical record. The surgical ICU physicians share this responsibility and the organ procurement group is also involved. The cardiac surgeons, SICU staff physician and staff anesthesiologist on call jointly decide whether it is feasible at the time to bring the brain dead donor to PUH. This decision must be made prior to the body's departure from the referring hospital.

The organ procurement group must notify all involved as soon as possible, and in advance, of the decision to bring a brain dead body to PUH. Those to be notified are: 1) emergency department; 2) admission office; 3) ICU staff physician on call; 4) ICU charge nurse; 5) operating room; and 6) staff anesthesiologist on call.

At the referring hospital, the organ procurement officer, dispatched from UHCP, reviews the medical record of the organ donor, the criteria used for determination of brain death and the result of this evaluation. This individual reports by phone to the PUH SICU staff physician the condition of these documents so that the SICU physician may determine, in advance, the acceptability of the donor body at PUH.

The following steps are finally taken at PUH:

1) Emergency Department (ED): The body is accepted at PUH and an identification number is assigned. The estate of the deceased must not be billed for any expenses incurred at PUH.

2) Intensive Care Unit: From the ED, the body is transferred to the SICU for continued cardiopulmonary support and monitoring. An SICU staff physician with experience of brain death evaluation and certification

reviews the following documents which accompany the patient: 1) copy of medical record from referring hospital; 2) copy of criteria used for brain death certification (unless reviewed and approved by PUH in advance); 3) copy of death certificate; 4) copy of consent for organ removal. The organ procurement group is responsible for obtaining and bringing these four documents with the body to PUH. The SICU staff physician writes a progress note in the medical record of the donor at PUH, indicating that all documents are in order and in agreement with current medical practice regarding certification of death based on irreversible cessation of all brain function.

3) Operating Room: The attending anesthesiologist provides cardiopulmonary support and fluid administration as indicated for continued optimal condition of the extracranial organs. When the surgical procedure for removal of all organs scheduled for harvesting has been completed, the body is sent to the morgue.

4) Morgue: The usual procedure is followed for notification of those responsible for proper disposition of the body.

The procedure described above permits removal of the heart and lungs during optimal conditions utilizing cardiopulmonary bypass. When these organs have been harvested, hypothermic perfusion is continued during removal of the liver, kidneys and any other desired organ. Thus, the technique described permits optimal procurement of multiple organs for transplantation. However, we find strict adherence to carefully written and previously approved policies and procedures to be of greatest importance for this activity, especially since the medico-legal responsibilities of the receiving hospital are presently unclear, should brain death certification of the transferred donor for any reason be erroneous as has happened in the past (10).

The heart transplantation program at the University Health Center of Pittsburgh was initiated in June 1980. Since then 40 patients have been transplanted with 26 survivors and a calculated actuarial three year survival time of 50%. Liver transplantations were commenced in February of 1981 and to date 107 patients have undergone 138 transplantations with 81 survivors (78%). Kidney transplantations have been performed since the late 1960's. After inclusion of cyclosporin A in the immunosupression therapy in 1981, 201 patients have received 204 transplants with 154 were primary and 50 retransplantations. In this material, there have been 12 deaths, i.e. 95% patient survival (graft survival 83%). In 1983, two pancreas transplants have been performed with survival of both patients. Combined heart and lung transplantations started in 1982 and so far 4 patients have been transplanted with 2 survivors.

It is particularly for transplantation of heart and lungs as one combined organ system that the donors have been transferred to our medical center for the purpose of multiple organ procurement. This was not done in our first case of heart and lung transplantation. The donor organs were procured at 180 miles distance from Pittsburgh after infusion of cold electrolyte solution and then transported by air to our hospital. Transplantation took place after 150 minutes of cold ischemia time. The lungs failed completely with severe pulmonary edema leading to the patient's death after three days in spite of heroic efforts including extracorporeal membrane oxygenation. In the subsequent three cases, the donor was transferred to PUH with greatly improved organ preservation. In these three cases, the hearts and lungs functioned well from the onset. Postoperative weaning from mechanical ventilation was uncomplicated although one of these three patients later died from sepsis. The other two remain survivors in excellent condition after three and six months at the time of this presentation.

Because of the large number of transplantations performed at the University Health Center of Pittsburgh and 15 years of experience with evaluation and certification of brain death a well functioning policy for certification of death based on irreversible cessation of all brain function has been established (11, 12). This policy was recently modified to include the special circumstances related to transfer to PUH of brain dead organ donors. Further, separate guidelines have been approved by the hospital executive committee for management of such referred brain dead organ donors.

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Presbyterian-University Hospital of Pittsburgh
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CHECK LIST FOR DIAGNOSIS OF BRAIN DEATH

NOTE: The patient must be observed in the hospital during treatment of potentially correctable abnormalities (e.g. hypovolemic shock). Two clinical examinations must then be performed; the second no sooner than two hours after the first.

CLINICAL EVALUATIONS

	#1	#2
Date of Exam:	______	______
Time of Exam:	______	______

A. Coma of established cause and absence of hypothermia (below 34°C) and central nervous system depressant drugs. A blood ethanol level and/or other appropriate toxicology studies should be performed if indicated. Body temperature should be recorded:

1. Body temperature: .... ______ ______
2. Blood ethanol: .... ______ ______
3. Toxicology studies: .... ______ ______

B. No spontaneous muscular movements and no evidence of decerebrate or decorticate posturing or shivering (in the absence of muscle relaxants): .... ______ ______

C. Cranial Nerve Reflexes and Responses:

1. Pupils light-fixed: .... ______ ______
2. Absent corneal reflexes: .... ______ ______
3. Unresponsiveness to intensely painful stimuli, e.g. supraorbital pressure: .... ______ ______
4. Absent response to upper and lower airway stimulation, e.g. pharyngeal and endotracheal suctioning: .... ______ ______
5. Absent ocular response to head turning (no eye movement): .... ______ ______
6. Absent ocular response to irrigation of the ears with 50 mls. of ice water (no eye movement): .... ______ ______

D. Absence of spontaneous breathing movements for 3 minutes and $PaCO_2$ above 60 torr at end of test (in absence of muscle relaxants). If a history suggestive of dependence on a hypoxic stimulus for ventilation (e.g. a COPD patient) is present, the PaO_2 at end of test must be less than 50 torr.

1. $PaCO_2$ at end of apnea test: .... ______ ______
2. PaO_2 at end of apnea test: .... ______ ______

E. An isoelectric electroencephalogram recorded in part at full gain: .... ______

F. Failure to increase heart rate by more than five per minute following atropine sulfate intravenously in a dose of 0.04 mg/kg:

1. Heart rate before atropine: .... ______ ______
2. Heart rate after atropine: .... ______ ______

G. Comments: ______________________________

CERTIFICATION OF DEATH

Having considered the above findings, we hereby certify the death of:

____

Date: ______________ Time ______________

Physicians' Signatures ______________ MD ______________ MD

Names Printed: ______________ MD ______________ MD

This document should be signed by two physicians licensed by the State of Pennsylvania.

PRESBYTERIAN-UNIVERSITY HOSPITAL

POLICY MANUAL

PAGE: 5108

INDEX TITLE: Patient Care

SUBJECT: Certification of Death Based on
Irreversible Cessation of All Brain
Function Including that of the Brain Stem

DATE: February, 1983

POLICY

It is the policy of Presbyterian-University Hospital while assuring optimal medical care to all patients to recognize that under certain circumstances, all medical therapy and life support shall be withdrawn after certification of patient death, including those patients in whom total and irreversible cessation of brain function can be clearly demonstrated according to the criteria listed below.

CRITERIA

The patient must be observed for an appropriate period of time in the hospital ICU during treatment of potentially correctable abnormalities which may contribute to deteriorated brain function, e.g. hypovolemia, hypoxemia, hypotension, hypothermia and presence of CNS depressant drugs including alcohol.

The cause of coma must be established and be sufficient to explain irreversible cessation of all brain function.

A check list of criteria is attached for the diagnosis of brain death (originally approved by the Executive Commmittee of Presbyterian-University Hospital in April, 1969, PUH: form number 900) and must be utilized in the brain death evaluation and certification process.

In those cases where a donor is transferred to PUH following Certification of Brain Death at another hospital, the Death Certificate must accompany the body and this must be documented by a PUH staff physician.

Only when organs are donated for transplantation purposes will cardiopulmonary and other essential organ support continue after death until donated organs have been removed.

PROCEDURE

A. When drugs may be implicated by the history of physical examination as a possible etiology of depressed brain function or in patients with coma of unknown etiology, toxicological screening and/or analysis for specific drugs are indicated. If, in addition, alcohol has been ingested, the synergistic effect between alcohol and such drugs must be considered and blood alcohol levels obtained. Recent general anesthesia, metabolic encephalopathies, encephalomeningitides, hypothermia and shock may also influence the brain injured patient's response during evaluation for potential brain death. Drugs known to be associated with an isoelectric EEG include barbiturates, methaqualone, diazepam, mecloqualone, meprobamate and trichlorethylene (JAMA 236:1123, 1976). Blood levels of all such agents must be absent or below therapeutic levels before brain death can be certified. Similarly, if neuromuscular blocking agents have been used, absence of the effects of these muscle relaxants must be secured by use of a nerve stimulator, before the examination can proceed.

Two separate clinical evaluations must be completed as prescribed in the stated criteria. The second may be conducted no sooner than two hours after the first. If any evidence of brain function is elicited during either examination, the patient does not fulfill the criteria and cannot be certified dead. Specific details relevant to the examination process include:

B. True decorticate or decerebrate posturing indicates brain stem function and excludes the diagnosis of brain death. However, complex muscle movements resembling decerebrate posturing but emanating from high spinal cord reflexes have been reported. Simple and complex spinal cord reflexes are often preserved in brain death and, being irrelevant to its diagnosis, are therefore not tested. Shivering indicates function of the temperature regulating center in the hypothalamus and also rules out the diagnosis of brain death.

C. 1. The pupils need not be equal or dilated but must be nonreactive to light stimulation. The pupillary reflex may be unreliable after the use of scopolamine, opiates, neuromuscular blocking agents, atropine, mydriatic eye drops, glutethemide and in the presence of eye trauma or disease, e.g. lens cataracts. The cilio-spinal reflex is not included in this testing.

2. The corneal reflex may be absent due to pre-existing severe facial weakness.

3. Painful stimuli are administered over the areas of cranial nerve distribution and not peripherally where spinal cord reflexes may be active.

4. Function of the glossopharyngeal and vagus nerves and their brainstem nuclei is tested through insertion of a pharyngeal and endotracheal suction catheter. Any gagging or coughing indicates remaining brainstem function.

5. The dolls eye phenomenon is tested through rapid head turning from side to side. If resulting in eye movement, this indicates remaining brainstem function.

6. The volume of ice cold water used for caloric stimulation should be 50 ml given with the patient's head at 30 degrees elevation slowly into each external ear canal free of

cerumen. This stimulus must be followed by several minutes of observation for any movement of the eyes. Pre-existing labyrinthine disease may abolish this reflex as might sedatives, anticholinergics, anticonvulsives, tricyclic antidepressants and ototoxic effect of certain antibiotics.

D. The apnea test is most important. The absence of spontaneous breathing tested during disconnection from the ventilator in the absence of muscle relaxants, necessitates documented PaC02 above 60 torr and arterial pH below 7.30. If a history suggestive of dependence on a hypoxic stimulus for ventilation (e.g. a COPD patient) is present, the Pa02 at the end of the test must be less than 50 torr. Otherwise, an endotracheal catheter with a 3-4 l/min 02 flow may be used to avoid cardiac arrest due to hypoxemia, of particular importance in patients considered candidates for organ donation.

E. A single isoelectric electroencephalogram (EEG) is required. This EEG is usually obtained after the first complete clinical examination without identified brain activity. Technical guidelines for recording the EEG to insure maximal machine sensitivity have been established by and are the responsibility of the Department of Neurology. The interpretation of the EEG as isoelectric must be made by an attending staff neurologist or Neurology Resident who has completed the EEG Rotation and made available in writing before death certification can be completed. If the EEG is not isoelectric, the patient does not fulfill the necessary criteria and cannot be certified dead. If recorded activity is suspected to be of muscular rather than cortical origin, a muscle relaxant may be used for clarification. However, the effect of utilized muscle relaxants must be worn off or reversed prior to the second clinical evaluation of brain function.

F. Inactivity of the vagus nerve nuclei is inferred from unresponsiveness of the heart rate to an intravenous atropine bolus.

G. The abnormalities observed during the performed brain death evaluation should be noted on the check list. For instance, bizarre, complex arm movements are occasionally observed and may necessitate vertebral arteriography to rule out sustained function of the brain stem.

CERTIFICATION

After the above diagnostic criteria have been completed, showing no evidence of continuing brain activity, the patient shall be certified dead. Such certification must be made by two physicians, licensed by the State of Pennsylvania. Members of the transplantation team may not be involved in death certification of a brain dead organ donor.

Brain death certification is equivalent to the pronouncement of death and the time documented for this certification is considered the time of death to be used for all legal matters including the Death Certificate issued by the hospital.

The pronouncement of death is by law a medical act. Therefore, consent is not required nor is it to be requested from the next-of-kin. However, the patient's family must have full information concerning this certification process.

In those cases wherein the Coroner has jurisdiction, his permission is not required for the death certification process or termination of medical therapy. However, the Coroner's consent must be obtained for removal of organs for transplantation.

When a brain dead donor of organs is transferred to PUH and Certification of brain death is made at the referring hospital, the referring institution will send a copy of the Death Certificate. This document will be made part of the donor record.

When organs are to be removed from a brain dead donor for the purposes of transplantations, death certification must be completed prior to removal. Removal of organs for transplantation must be preceded by consent from the next-of-kin (PUH Form No 874 or transferring hospital's equivalent form) unless the deceased has legally certified such donation. When transferred from another hospital, the donor body shall be placed in the ICU unless taken directly to the Operating Room and the Admitting Department will be notified.

A donor number will be assigned by the Admitting Department to each donor body received by this hospital. The donor acceptance process will not involve admission to the hospital. The donor number will be utilized for the coordination of medical documentation relating to the donor body and appropriate expense charges.

Those hospital policies and procedures concerning matters relevant to any deceased patient (i.e., death, autopsy and coroner cases, Policy #4001, etc.) apply equally to these patients after completion of the certification process and removal of all medical therapy or life support devices.

Members of the Critical Care Medicine Program are available at all times for the interpretation of this policy and the completion of the certification form.

SIGNED: D. L. Stickler
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    ICU Subcommittee: November, 1982
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BRAIN DEATH AND PERMANENTLY LOST CONSCIOUSNESS

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BRAIN DEATH

Both the medical and legal professions traditionally have equated death of the patient with irreversible cessation of respiratory and cardiovascular functions. However, since the 1970's, legislation has attempted to define death as the irreversible cessation of all brain function, i.e. brain death (1). Thus, irreversible cardiac arrest, which can be treated by insertion of an artificial heart or cardiac transplantation, leads to death of the individual only when brain function ceases.

The clinical definition of brain death is the permanent loss of all integrated neuronal brain functions (2, 3). The term integrated is important since recovery of some metabolic and electrical activity in the brain following even 60 minutes of total ischemia has been demonstrated experimentally (4). It is also important to realize that there is a difference between cerebral death (18) and brain death (7): in the former, parts or all of the brainstem, pons, midbrain and cerebellum can still function; in the latter, all brain structures above the foramen magnum have irreversibly ceased to function. So far, only brain death has been medically and legally equated with death. Once there is medical proof that all brain function has irreversibly ceased, both ethical and religious viewpoints (5, 6), support death certification and cessation of all treatment.

Specific criteria for determining brain death have been independently developed by many different groups (3, 7, 8). While these guidelines differ regarding individual tests recommended, all require a detailed, careful neurologic examination that usually includes an electroencephalogram (EEG). Repeat evaluations may or may not be demanded but re-examination after specified time intervals is usually recommended. Suggested intervals range from 30 minutes to 24 hours and often vary with the etiology of coma (7-12, 18-21). On the other hand, brain death may be certified after a single examination in patients with a known cause for irreversible and complete loss of all brain function (3, 22, 12, 14, 17).

Recent guidelines from the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research include two statements concerning the criteria for determination of death : A) An individual with irreversible cessation of circulatory and respiratory function is dead; and B) An individual with irreversible cessation of all functions of the entire brain, including the brainstem, is dead (30). However, further analysis of these two statements indicates that irreversible cessation of brainstem function is the crucial issue in both. In a patient with discontinued heart beats, cessation of the function of the respiratory center in the brainstem is necessary to stop spontaneous breathing in order to meet the criteria of death. A patient with high cervical spinal cord injury, is an exception to this general rule.

In patients supported by mechanical ventilation cardiac arrest usually occurs within 72 hours of brain death (18, 22-24). However, a recent publication (25) reports a patient with verified brain death, maintained for 68 days on mechanical ventilation, before cardiac arrest finally occurred. Theoretically, it is possible for extracranial organs in a brain-dead body to function indefinitely, until old age wears out the heart. In other words continued intensive therapy of brain dead bodies, if generally applied, could effectively drain our medical and economical resources. Nonetheless, temporary continuation of intensive therapy after certification of brain death is still indicated in two situations: when removal of organs is to take place for transplantation purposes and when the brain dead individual is a pregnant female with a viable fetus (26).

The criteria for determination of death based on irreversible cessation of all brain function, listed in the guidelines by the President's Commission (30), require documentation that: 1) cerebral and brainstem functions are absent; 2) this condition is irreversible which necessitates known cause of the condition and exclusion of the possibility of recovery; and 3) the cessation of all brain functions persists for an appropriate period of observation and/or trial of therapy.

To avoid confusion between brain death and the so-called persistent vegetative states (31), the President's Commission guidelines (30) advise that the criteria physicians use in determining that death has occurred should 1) eliminate errors in classifying a living individual as dead; 2) allow as few errors as possible in classifying a dead body as alive; 3) allow a determination to be made without unreasonable delay; 4) be adaptable to a variety of clinical situations; and 5) be explicit and accessible to verification.

It is obvious from the above that both cortical and brainstem functions must be cautiously examined and the need for this clearly stated in any criteria adopted for determination of brain death. Most causes of brain death (Table 1) are demonstratable on computed tomography. However, total life-support should continue while attempts are made to identify any reversible etiology of depressed brain function. A hospital's policy for evaluation and certification of brain death must require that the patient be observed and treated for potentially correctable abnormalities with seemingly absent brain function. Conditions which may significantly contribute to absent brain function include hypovolemia, hypoxemia, hypotension, hypothermia, any form of shock, and presence of central nervous system depressants, such as sedatives, narcotics, anticonvulsants, anesthetics or alcohol.

If a toxic, metabolic, pharmacologic, infectious or other cause of potentially reversible coma is identified, the brain death certification process must be suspended while appropriate therapy is instituted or continued. For instance, deep hypothermia, especially in combination with drug overdose (33) or acute alcohol intoxication (34), is a condition which has been mistaken for death but careful resuscitation has resulted in survival. Further, different forms of shock, if present, will aggravate any co-existing cerebral dysfunction, e.g. in multiple injury (19) and must therefore be vigorously treated before brain death evaluation takes place (3).

When drugs may be implicated by the history or physical examination as a possible etiology of depressed brain function, detailed toxic screening tests are indicated. If alcohol has been ingested, the synergistic effect between alcohol and such drugs must be considered and blood alcohol levels obtained as well. Sedative drugs known to be associated with an isoelectric EEG include barbiturates, methaqualone, diazepam, mecloqualone, meprobamate and tricholorethylene (32). Blood levels of such agents must be absent or below therapeutic range before brain death evaluation can be performed. However, drug metabolism and excretion may be very slow in brain dead patients, resulting in several days of continued futile therapy in some cases, e.g. when administration of large doses of barbiturates has been used for control of intracranial hypertension. In such cases, we utilize documentation of complete absence of cerebral blood flow as the ultimate criterion of brain death. This can most easily be done through bilateral internal carotid and vertebral arteriography but radionuclide cerebral imaging has recently been demonstrated as a less complicated procedure of similar value which can be performed at the bedside in the ICU (35).

The criteria for brain death used at Presbyterian-University Hospital (PUH) in Pittsburgh (Figure 1 and Appendix) include complete absence of cerebral and brainstem activity on two clinical examinations, performed at least two hours apart, plus a single, maximally sensitive, isoelectric EEG (27). This EEG must be recorded with and without auditory stimulation for a minimum of 30 minutes and at least part of this test must use an amplification factor of two microvolts per millimeter. The EEG is usually performed between the first and second clinical examinations. Neuromuscular blockade with succinylcholine, pancuronium or similar agents may be used to abolish muscle artifacts which interfere with the EEG tracing but the muscle relaxing effects of these agents must be absent before the subsequent clinical examination. This can easily be tested with an electric nerve stimulator, of the type routinely used in anesthesiology.

The clinical part of the evaluation is a standardized neurological examination of cranial nerve activity and an appropriate apnea test to detect signs of spontaneous breathing. If there is any sign of brain function during either clinical examination, death cannot be certified.

Normally, painful stimuli are administered over the areas of cranial nerve distribution rather than peripherally, since spinal cord neurons may remain viable after brain function has ceased (20, 22). True decorticate or decerebrate posturing indicates brainstem function and therefore excludes the diagnosis of brain death. However, complex muscle movements resembling decerebrate posturing but emanating from high spinal cord areas have been reported (3, 20). A simultaneous EEG recording may be useful in confirming that cortical structures are not involved in such movements although an isoelectric EEG does not necessarily exclude minimal function of the brainstem, pons and midbrain, known to be responsible for certain primitive reflexes e.g. in newborns. Although simple and complex spinal cord reflexes are often preserved in brain death, they are irrelevant to its diagnosis and therefore not tested. However, shivering indicates function of the temperature regulating center in the hypothalamus and rules out the diagnosis of brain death.

The pupils need not be equal or dilated but must be nonreactive to light stimulation. However, absence of the pupillary reflex is nondiagnostic after administration of scopolamine, opiates, neuromuscular blocking agents, atropine, mydriatic eye drops or glutethemide as well as in the presence of eye trauma or disease, e.g. lens cataract. The ciliospinal reflex is not included in this testing, since it is not a cranial nerve reflex. The corneal reflex, on the other hand, is tested but may be absent due to pre-existing and severe facial weakness.

Function of the glossopharyngeal and vagus nerves and their brainstem nuclei is tested through insertion of a pharyngeal and endotracheal catheter. Any gagging or coughing indicates brainstem function. The doll's eye phenomenon is tested by rapidly turning the head from side to side and any eye movement indicates brainstem function. This test must be used cautiously, since it may excerbate any pre-existing cervical spine injury. Similarly, testing the ocular response to irrigation of the ears with ice water may be contraindicated by injuries to the inner ear. When this test is undertaken, the patient's head should be at 30° elevation and 50 ml of ice water are injected slowly into each external ear canal, which must be free of cerumen. This stimulus should be followed by several minutes of observation for eye movement. Pre-existing labyrinthine disease may abolish this reflex as may sedatives, anticholinergics, anticonvulsives, tricyclic antidepressants and the ototoxic effect of certain antibiotics.

The apnea test is extremely important. Apnea is defined as the absence of spontaneous breathing during disconnection from the ventilator with an arterial carbon dioxide tension greater than 60 torr and an arterial pH below 7.30 at the end of the test. Of course, this necessitates absence of muscle relaxants. If the patient's history suggests dependence on a hypoxic stimulus for ventilation such as in chronic obstructive pulmonary disease (COPD), the arterial oxygen tension at the end of the test must be less than 50 torr. Otherwise, an endotracheal catheter with an oxygen flow of 3 to 4 L/min may be used to avoid cardiac arrest due to hypoxemia which is a complication of particular importance in patients being considered as organ donors.

The most recent problem encountered in brain death certification is the transport delay caused by conflicting criteria among hospitals transferring dead patients for multiple organ harvest and transplantation (29). For transplantation of hearts, kidneys or livers, donor organs may be retrieved at a distance from the transplant center. Kidneys are kept viable in hypothermia with specially designed perfusion machines. Hearts and livers are chilled by perfusion of hyperosmolar solutions at $+4^{\circ}C$ and transported cold, sometimes thousands of miles by charter or private jet air craft. While ischemia time is variably prolonged, risks to donor organs are generally acceptable. However, in combined transplantation of heart and lungs, the lungs are more prone to ischemic injury. For such transplantation, ischemia time is minimized by harvesting organs at the transplant center. When a brain dead donor is transferred to PUH in Pittsburgh, death certification must be performed at the referring hospital. Brain dead donors are accepted only from hospitals where criteria of brain death have been scrutinized in advance by our staff and found acceptable. The body is registered at the hospital by number in contrast to being admitted and is placed in the ICU for full cardiopulmonary support. This procedure permits removal of the heart and lungs during optimal conditions utilizing cardiopulmonary bypass. When the heart and lungs have been removed, hypothermic perfusion is continued during removal of liver and kidneys. Thus, the technique described permits optimal procurement of multiple organs for transplantation. However, we find strict adherence to carefully written and previously approved policies and procedures to be of greatest importance for this activity, especially since the medical legal responsibilities of the receiving hospital are presently unclear, should brain death certification of the transferred donor for any reason be erroneous as has happened in the past (20).

PERMANENTLY LOST CONSCIOUSNESS

Permanently lost consciousness denotes a condition between life and death. Such individuals are not brain dead nor able to return to a cognizant life. There is severe neurological dysfunction with only minimal persisting brain activity. These conditions must be excluded from certain medullo-pontine lesions causing the so-called locked in syndrome, also referred to as akinetic mutism, paralytic akinesia and cerebro- medullospinal disconnection. In the latter condition, some mental awareness may be preserved and significant cranial nerve dysfunction exists but voluntary muscle movements are absent (38-40).

Permanent unconsciousness occurs in five different conditions: 1) persistent vegetative states; 2) coma after brain injury or hypoxia without brainstem function; 3) endstate degenerative brain disease (e.g. Jacob-Creutzfeldt's and Alzheimer's diseases); 4) intracranial mass lesions; 5) congenital brain hypoplasia (anencephaly) (44). However, permanent unconsciousness is often referred to by other terms. Thus, Ingvar et al (41) describe what they call the apallic syndrome. This term was first introduced by Kretschmer in 1940 (45), pallium meaning the mantle of the telencephalon, i.e. the cerebral cortex. Mollaret and Goulon in 1959 (33) coined the expression coma prolonge. Jennett and Plum in 1972 (31) referred to this as the persistent vegetative state and Brierly et al in 1976 (46) called it neocortical death. Finally, Korein in 1978 (18) used the expression cerebral death which is not identical to brain death, since the midbrain, pons, brainstem and cerebellum partially or totally are intact. However, for all practical purposes, the above terms can be considered synonymous.

In their publication of 1978, Ingvar et al indicate that these apallic syndrome patients after a few weeks become arousable whereas comatose patients by definition are nonarousable. Thus, these patients, while no longer in coma, nonetheless are unconscious. All higher functions are absent such as speech, voluntary movements, emotions and memory. Brainstem reflexes on the other hand are usually present such as spontaneous breathing. Although the patients are arousable, they respond to stimuli with primitive functions only, such as eye opening, chewing and changes in respiratory rate and rhythm. On electroencephalography, electrical activity is typically present but severely depressed.

The etiology of the apallic syndrome is usually cerebral anoxia which may be caused, for instance, by global ischemia in prolonged cardiac arrest, cerebral hypoperfusion in shock conditions or complete absence of cerebral blood flow during periods of intracranial hypertension. While the sensitive neurons in the neocortex die secondary to the above, brainstem function may be surprisingly well retained. With time, there is severe cortical atrophy with enlargement of the ventricular system. Clinically, such conditions are demonstrable at computerized tomography and ultrasonic examination of the brain as a gigantic ventricular system with a thin layer of tissue left, where normally the cerebral cortex would be found.

The characteristics of permanently lost consciousness has been excellently described as follows: "Personality, memory, purpose of action, social interaction and emotional states are gone. What remains is a bodily reminder of a person who once was and might yet have been. Only vegetative functions and reflexes persist. If food is supplied, the gut functions and uncontrolled evacuation occurs; the kidneys make urine and the bladder is incontinent; the heart, lungs and blood vessels continue to move air and blood; nutrients are distributed in the body and CO2 and O2 are exchanged." (44)

Unfortunately, there is a common misunderstanding in today's medical society that as long as there is any sign of life, every patient in the intensive care unit must be treated maximally. However, as Childress describes "optimal care does not always mean maximal treatment. Caring continues even when the patient is allowed to die" (43). Childress continues: "every person has the right to die, i.e. the right of noninterference, but not the right to be killed e.g. through a claim to another person's assistance. For the physician, the benefit to the patient is paramount; treatment must be in the patient's best interest."

Veatch (42) suggests that the whole brain death concept is outmoded. In his words, "death is the irreversible loss of what is essentially significant to the nature of man, including the capacity: to integrate bodily function, for rationality, to experience, and for social interaction." In 1981, the AMA Judicial Council indeed expressed as its opinion that "Where a terminally ill patient's coma is beyond doubt irreversible and there are adequate safeguards to confirm the accuracy of the diagnosis, all means of life support may be discontinued." Through clinical examination, cerebral arteriography, CT scanning and ultrasonic examination of the brain, it is possible to demonstrate total loss of the cortical layers and thus verify the irreversibility of the patient's unconsciousness, although several weeks must pass before such documentation can take place. In these conditions, life sustaining therapy is no longer of any benefit to the patient and thus not indicated. If not indicated, such therapy should be withdrawn just as all other no longer indicated therapy is discontinued in clinical practice. Based on this important medical principle, there is no significant difference between withholding and withdrawing therapy.

Typical examples of life sustaining therapy include mechanical ventilation, vasopressor infusion and use of intra-aortic balloon pumping. However, most discussion has concentrated on the use of mechanical ventilation and "pulling the plug" of the ventilator in these conditions. Abrupt discontinuation of life supporting therapy such as mechanical ventilation might be interpreted as an act committed with intent to kill. Therefore, in Pittsburgh, we have developed a different technique referred to as "terminal weaning" (47). It is important to understand that when death follows terminal weaning, the patient dies from natural causes due to his or her lethal disease and not from an act of killing by the responsible physician.

The difference between terminal weaning and regular weaning from life supporting therapy is that terminal weaning proceeds in spite of deteriorating vital signs and other monitored variables. For instance, during terminal weaning from mechanical ventilation, we continue to analyze arterial blood gases in order to know how close the patient is to a final cardiac arrest or whether the patient may be able to maintain his or her own spontaneous breathing sufficiently for a temporary period of time. (Compare the situation of Karen Ann Quinlan when her mechanical ventilation was discontinued in 1976. She is still breathing spontaneously after seven years, although in a permanently unconscious state.)

Terminal weaning proceeds relatively quickly, over several hours rather than several days. Many patients die in this phase. A few survive to the point of spontaneous breathing and occasionally we are even able to extubate these patients. Some need to remain intubated to avoid sudden airway obstruction which again causes a relatively abrupt death rather than the intended quiet and peaceful death taking place over a few hours. Sometimes, a tracheostomy has been performed to avoid the airway obstruction/suffocation type of death. However, tracheostomy is now avoided, as this prolongation of life is of no benefit to the patient.

In those patients whose breathing pattern includes gasping or other signs that are distressful to observers, we provide increments of morphine intravenously, 1-2 mg at a time. The purpose is to decrease reflex response to hypoxia and also to reduce metabolism and thus oxygen demand. This form of therapy provides comfort to the relatives who wish to see their loved one die quietly without "signs of suffering". Further, it has a comforting effect on the personnel in the ICU. Arterial blood gas analyses are continued so that the attending physician will be better able to reasonably predict the moment of death, thus providing reliable guidance to present family members.

Once the decision has been made for limited therapy related only to hygenic care and comfort, it is important that one does not continue already started treatment which is no longer indicated. For instance, continuance in this phase of mechanical ventilation may very well postpone the moment of death by several days and occasionally weeks. This might give the relatives the impression that the physicians were mistaken in their information to them regarding the prognosis of the patient's condition. Further, many relatives, especially those who remain continuously in the ICU waiting room to be close to their dying relative, may develop sleep deprivation, irritation, disappointment, anger and even hostility against the hospital and its personnel, including the attending physician. However, if the physician remains confident in his overall analysis of the patient's condition and prognosis, having already in detail diagnosed the patient's primary disease and potential complications as well as carefully evaluated the related prognosis, he will indeed be able to provide the patient with this important opportunity to die peacefully, usually within a few hours, through the terminal weaning procedure. The relatives will then leave the institution grateful and satisfied. They will be aware of two things. First, everything possible was done for their loved one. Second, when it became obvious that there was no reasonable possibility for survival, all forms of treatment no longer indicated were discontinued or gradually withdrawn to finally permit the patient to die with dignity. Unfortunately, continued life sustaining therapy in these futile conditions is common, although it is exhausting and frustrating to relatives, exasperating to personnel, wasteful of resources and expensive to the nation.

The following steps are taken at Presbyterian-University Hospital in Pittsburgh during terminal weaning:

1. Continual respectful/hygenic care is provided throughout.
2. Continued close monitoring for prediction of moment of death, i.e. cardiac arrest.
3. The weaning proceeds over hours rather than days, regardless of deteriorating variables, e.g. arterial blood gases.
4. If disturbing gasping occurs, morphine sulfate, 1-2 mg IV, is given to decrease hypoxic reflex response, metabolism and oxygen demand and is repeated as indicated.
5. If airway obstruction is not expected, the patient is extubated once weaned off mechanical ventilation and breathing spontaneously.
6. If maintaining his airway without severe obstruction, the patient is discharged from the ICU to a private room in a regular ward where relatives may remain continuously with the dying patient.
7. The responsible physician remains in close communication with the relatives throughout.
8. The patient may die in any phase of the above and the relatives should be so informed in advance.

Pain and other forms of suffering, including the psychological aspects of life terminating in an ICU, is a threat especially to the elderly in our society. To some of them, the ICU becomes a modern torture chamber, where young physicians consider death their worst enemy and do not appreciate that it may be the old man's friend, when he has reached a point where he may indeed wish to die. Today, critical care physicians, nurses and other health care providers are extremely good at keeping terminally ill patients alive in the ICU with all modern forms of medical management, utilizing electronic and computerized equipment. However, the problem is that all that is done in many of these cases is to prolong the patient's dying.

When intensive care units were implemented many years ago, the emphasis was on resuscitation and continued life support. It has become increasingly obvious that diagnostic pursuit and determination of prognosis, especially as it relates to the brain, is of greatest importance in this situation. Critical care physicians will fail to serve mankind optimally if the wisdom of continued support is not always carefully considered in each case. It is definitely wrong to believe that every condition is curable. It is also wrong to continue life sustaining therapy of all ICU patients until cardiac arrest occurs and even worse to always perform cardiopulmonary resuscitation on all patients without distinction. Many modern physicans seem to have lost the understanding that death is a fact of life and will always occur. Some of us act as if life were eternal or at least may always be meaningfully prolonged. By attempting prolongation indiscriminately, much unnecessary suffering may occur among close family members. Fortunately, in persistent vegetative states these permanently unconscious patients are beyond suffering. This is true because these patients cannot experience suffering without a functioning cerebral cortex.

Physicians have the duty to sustain life and relieve suffering. However, with some dying patients, these duties will conflict and the choice to forego life-sustaining therapy in order to relieve suffering is justified (36). Since the patient with permanently lost consciousness is unable to suffer, it is important to consider the suffering of family members which takes place with an unduely prolonged death process. The participation of family members in the decision making process is necessary to maintain the trusting patient-family-physician relationship, once the patient is no longer able to take part in this process. Hesitation on the family members' part should be met with additional sensitive discussions and continued education, as indicated, concerning the patient's condition and the implications of changes in his or her status.

We have also seen cases in which relatives have requested withdrawal of treatment when the involved physicians consider the patient to have a sufficient chance of survival to warrant continued life support. In one extreme example, both the referring physicians and the relatives were led to believe that the patient had already succumbed due to irreversible cessation of all brain function. This was an 18-year-old man, admitted to our ICU with multiple injuries, including brain contusion following a severe automobile accident. He was referred from another hospital for the sole purpose of kidney donation with consent forms for removal of these organs already signed by the parents. However, since the patient was in hypovolemic shock, and had rudimentary cranial nerve reflexes, he did not meet our brain death criteria and total support was provided. He responded surprisingly well to vigorous resuscitation, including aggressive treatment of his hypovolemia, and was discharged from the hospital after two months with only relatively minor residual neurological deficits of right hemiparesis and some impairment of higher cognitive functions (20).

Initial aggressiveness, rapid diagnostic pursuit of underlying disease and/or all different injuries in trauma victims, alertness towards potential complications, and repeated evaluation of prognosis following a significant period of maximal therapy, are all important factors which must be considered before a decision is made to withdraw any therapy. Nonetheless, such decision should not be further delayed when the needed evidence is at hand that continued treatment is futile. Under these conditions, a shorter life and its satisfactions are expected to outweigh the appeal of prolonged life limited to an intensive care unit. However, guidelines must protect against untimely death, caused by temporary depression of the patient, erroneous decision and other flaws in the decision making process (36).

TABLE 1

Patients certified brain dead 1970-1976
Presbyterian-University Hospital
Pittsburgh, Pennsylvania

Etiology	No. (%)	Age Range	Age Mean
Cerebral bleeding	70 (39.8)	18-76	44
Trauma	58 (32.9)	11-65	30
Postresuscitation	20 (11.4)	17-89	48
Vascular occlusion	14 (8.0)	18-76	44
Tumor	6 (3.4)	22-62	48
Miscellaneous	8 (4.5)	16-54	43
Total	176 (100.0)	11-89	41

This table shows distribution of causes of brain death in 176 consecutive cases at Presbyterian-University Hospital in Pittsburgh (20).

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Mr. GORE. Thank you very much, doctor.

Our next witness is Dr. Richard Rettig, professor and chairman of the Department of Social Sciences at the Illinois Institute of Technology in Chicago.

Dr. Rettig, welcome.

STATEMENT OF DR. RICHARD A. RETTIG, PROFESSOR AND CHAIRMAN, DEPARTMENT OF SOCIAL SCIENCES, ILLINOIS INSTITUTE OF TECHNOLOGY

Dr. RETTIG. Thank you, Mr. Chairman.

I am at the Illinois Institute of Technology, as you indicated. I was with the Rand Corporation. With Jerome Aroesty at the Rand Corporation, I have been engaged in the past 15 months in a study of kidney transplantation and organ procurement.

My remarks today are based on that study. They represent the personal views of Dr. Aroesty and myself and not necessarily the views of either the Illinois Institute of Technology or the Rand Corporation. I will touch on some of the highlights of the study.

On July 1 of this year, the United States will mark the 10th anniversary of medicare coverage of end-stage renal disease. Within the context of this hearing, I will restrict myself to the kidney dimension.

That effort expended $228 million in direct medicare benefits in 1974, its first full calendar year of operation, and you heard from Dr. Davis this morning that the estimates for 1982 will be $1.8 billion.

The ESRD program is primarily a dialysis program. On December 31, 1982, HCFA reported that some 70,000 ESRD patients were entitled to medicare benefits for both dialysis and transplantation. They also reported that 65,000 medicare and non-medicare patients were receiving dialysis treatments on that date, of whom it is estimated 86 percent are currently entitled, 7 percent are in the initial waiting period, and approximately 7 percent are not entitled to medicare benefits.

In 1982, it was estimated that 12,000 patients were alive with a functioning kidney transplant. HCFA reported that 5,358 transplant procedures were performed in 1982. Of these, somewhat more than 70 percent came from cadaver donors; somewhat less than 30 percent from living related donors.

For 1981, of an estimated 3,600 cadaver transplant procedures, approximately 2,900 constituted first transplants, and approximately 700 represented retransplants; that is, second or successive transplants following failure of an initial transplant.

Potential transplant recipients are estimated by us to be approximately 22,500 or ⅜ of the dialysis population. Of about 20,000 patients each year who currently begin treatment for permanent kidney failure, about 8,000 are estimated to be suitable for transplantation.

Let me underline my next point, Mr. Chairman. It seems to me the reason we are here today is that it is widely believed within the transplant community that there is new era at hand in organ transplantation, and all the meaning attached to this hearing ought to be seen in light of that breakpoint that we anticipate—we have not yet seen—but that breakpoint of the future from the recent present and the past.

Survival of a transplanted cadaver kidney hovered for some time around the 50 percent 1-year post-transplant mark. A number of medical people in the nephrology community found that not particularly strong evidence of success. That cadaver kidney survival rate has clearly moved up, and it is because that has moved up, due to many factors but certainly to cyclosporine, that we are here today.

The question then becomes, if a new era of transplantation is at hand, what ought the Congress and the executive branch to be considering? Let me suggest the following:

First, that we set some reasonable objectives, or at least think about some reasonable objectives. When I say set reasonable objectives, I do not mean either a new statute, or new regulations. But we think it is reasonable to double the number of kidney transplant procedures over a 5-year period. This would mean, from a base of 5,000 now, an annual increment of 1,000 new kidneys per year so that by 1987 or 1988, transplant surgeons were performing 10,000 transplant procedures.

We are not predicting that this will happen. We think it is reasonable to set these objectives and to think about the problem in these terms.

Second, it should be recognized that there is a complex cost-saving phenomenon that occurs within the kidney transplantation domain, and it is sometimes at variance with those who intuitively think that transplantation successes can eliminate the entire dialysis population.

There are several reasons for this what would appear to be modest cost savings. These reasons include the substantial front-end costs associated both with the transplant procedure and organ procurement that dominate the patient cost profile and mask out-year savings.

Second, important cost savings from improved transplantation will have a relatively modest initial effect on the much larger dialysis population of the total end-stage renal disease program. So you are getting a big purchase, at the moment, on a fairly small portion of the total problem. The savings, however, will accumulate over time, and that is a very important thing to note.

The cost effects are likely to occur in three areas. Transplant successes may become less expensive. Data from Minnesota and Pittsburgh suggest less initial hospitalization days and reduced frequency of readmission. The variance from center to center may be quite substantial, and these cost savings may be offset somewhat by increased costs of medication. But that is one important source of potential savings.

Secondly, and something that is not discussed really very extensively in the literature, is the following: The cost of kidney transplant failure may be expected to decline. Failure of a transplant results in either death or return to dialysis.

In 1981, about 3,600 individuals received a cadaver transplant, as I said earlier, about 2,900 first transplants. Of these first transplants, it is estimated that 60 percent were alive with a functioning transplant 1 year later, 10 percent died, and about 30 percent returned to dialysis.

If transplant failure occurs and an individual does return to dialysis, the cost to HCFA of unsuccessfully treating rejection is approximately $3,500. The cost of removing the failed kidney when necessary—and it is frequently necessary—is approximately $10,000. The additional cost of the dialysis regime ranges up to $3,000 per year more than the normal dialysis patient.

So one would expect to cut into these costs by doing better, by reducing the number of failures, and these cost savings are available regardless of the scarcity or shortage of kidneys.

Third, the rate of growth of ESRD program costs will decrease over time as patients are successfully shifted from dialysis to transplantation.

Two summary points on this section: The ESRD program will remain primarily a dialysis program, but, secondly, improved transplantation results will have a beneficial cost effect, particularly over time.

The second thing we can do is to improve organ procurement. Dr. Prottas will address some of these issues, but I have the following comments to make about strategies to increase the number of cadaver kidneys retrived and used.

First, increase the interaction of organ procurement teams with source hospitals in a way consistent with the methodology described by the Centers for Disease Control.

Second, it would be prudent and worthwhile to examine the relationship between those kidneys retrieved and those actually used. Currently, 20 to 25 percent of retrieved kidneys are not used for a variety of reasons, and attention needs to be addressed to this.

Third, we believe that the experience of CDC in the late 1970's deserves reevaluation. I wish to make a very important point here. Practically all interpretations of that experience point to the benefits of using the CDC methodology or systematizing the process. We believe that benefit is very important. But quite often and usually overlooked has been the fact that the CDC experience also had a second dimension, and that is, CDC invested additional resources into the locations where they developed their methodology. The point is this: If you invest more in organ procurement, you may receive more kidneys as a consequence. That proposition, to our knowledge, has not been examined. It is a very important point. We reimburse on a per-kidney acquired basis. That may be suboptimal relative to the entire program. That is about $7,000 per kidney, on the average, is spent by HCFA. If that figure rose for example, to $9,000 or even higher it would be worth examining what the effect would be in more organs received on the other side.

Fourth, if the results of transplantation improve, the country should take advantage of this through public education that disseminates widely the information about this improvement. We believe that altruistic behavior in the form of voluntary donations of kidneys may relate to the perception of the probability of successful outcome from transplantation.

There was a Gallup poll taken in January of this 1983. The results were reported by the National Kidney Foundation in February. A national sample of 1,500 individuals showed that 49 percent believed that the donation of a kidney "could extend that person's life substantially" that is, the recipient's life; but 42 percent expressed uncertainty that receiving a kidney "might or might not" extend that person's life.

Of those who expressed greatest confidence about the benefit, 60 percent expressed the willingness to permit the donation of their own kidneys. For those indicating greater uncertainty about the effects of transplantation, only 36 percent expressed a willingness to donate kidneys.

It might reasonably be expected, therefore, that if outcomes improve and the perception of improved outcomes increases, a corresponding increase in willingness to donate will occur.

It might further be expected, therefore, that we would witness a shift in attitudes, intentions, and behaviors that result in increased organ donations.

There are many qualifications to this, but the basic line of argument is that altruistic behavior is predicated on the perceived likelihood that the donated kidney will usefully prolong life. Public policy should emphasize this and not prematurely deem altruism a failure.

Fifth, and a corollary to the above, presumed consent laws should not receive high priority. There are important ethical and social aspects that deserve full debate. But simply as a practical matter, it is a long, complex process to change the laws of 50 States. 1970 was when the first State adopted brain death legislation. Thirty States have done so today. Illinois is on the threshold of doing so. New York has yet to do so.

Presumed consent laws, we anticipate, would follow that same lengthy process. We should devote our energies more usefully to improving the present system.

What are the policy implications?

If a new era in transplantation as a treatment for end-stage renal disease is at hand, at least five specific policy issues deserve attention.

First, Congress should examine the issue of reimbursing immunosuppressive drugs used by transplant recipients for outpatient services. That issue deserves very, very careful attention by the Congress, because the current law precludes HCFA from reimbursing medications prescribed for the outpatient setting.

Second, Congress should eliminate the 3-year limitation on the eligibility for benefits for the successful transplant recipient. The initial 1972 law limited benefits to 12 months; the 1978 legislation lengthened the time to 3 years. The legislative history is practically nonexistent, and there is no basis in equity for patients, nor a posture of neutrality among treatments, to justify that limitation.

Third, Congress and the executive branch should examine the proposition that increased resources invested in organ procurement might well yield higher numbers of retrieved kidneys.

Fourth, Congress and the executive branch should recognize that the capability of the Federal Government to administer the end-stage renal disease program is so weak that both the Congress and the executive branch should search for ways to promote learning within the administratively decentralized, geographically dispersed organ procurement and kidney transplantation system. I cannot underline this more strongly. Not much help is going to come from the Federal Government.

In 1981, in September, before Senator Durenberger, in addressing aspects of this program, several of us advised that the Health Care Financing Administration should not disestablish the Office of Special Programs and the Office of End-Stage Renal Disease. We did not know this hearing would be held this month, but we predicted that some hearing would be held in the future and that the administrative capability to deal with these issues should exist.

In the absence of that capability, conferences, seminars, and learning should be nourished and encouraged wherever possible across the country.

Finally, I would concur with the comments made this morning that the current institutional mechanisms for assessing the nature and implications of new developments in medicine, like improved transplantation, are so weak that they demand reevaluation.

I hope these remarks help these deliberations on this subject of organ procurement and transportation.

Thank you.

[The prepared statement of Dr. Rettig follows:]

Testimony of

Richard A. Rettig, Ph.D.

Representative Gore, Members of the Subcommittee.

My name is Richard A. Rettig. I am Professor of Social Sciences and Chairman of the Department of Social Sciences at the Illinois Institute of Technology. I am also a consultant to, and a former employee of, the Rand Corporation. In this latter capacity, with Dr. Jerome Aroesty of Rand, I have been engaged for the past fifteen months in a study of kidney transplantation and organ procurement.

My remarks today are based upon that study. They represent the personal views of Dr. Aroesty and myself and do not necessarily represent the view of either the Illinois Institute of Technology or the Rand Corporation.

On July 1 of this year, the United States will mark the 10th anniversary of Medicare coverage of end-stage renal disease. That effort expended $228.5 million in direct Medicare benefits in 1974, its first full calendar year of operation. Preliminary figures from the Health Care Financing Administration show 1982 Medicare expenditures of $1,540.1 million, and it is reasonable to expect that the final figure will reach $1.7 billion or higher.

The ESRD Program is primarily a dialysis program. On December 31, 1982, HCFA reported that 70,055 ESRD patients were entitled to Medicare benefits. HCFA also reported that a total of 65,763 Medicare and non-Medicare patients were receiving dialysis treatments on that date. Of this number, it is estimated that 86 percent are currently entitled to benefits, 7 percent will be entitled after fulfilling the initial waiting period requirement, and 7 percent are not entitled to Medicare benefits.

In 1982, an estimated 12,000 ESRD patients were alive with a functioning kidney transplant. HCFA reported that 5,358 transplant procedures were performed; of these somewhat more than 70 percent came from cadaver kidney donors and somewhat less than 30 percent were received from living-related donors. For 1981, of an estimated 3,600 cadaver transplanted procedures, approximately 2,900 constituted first transplants and approximately 700 represented retransplants (second or successive transplants following transplant failure).

Potential transplant recipients are estimated to be 22,500, or three-eighths of the dialysis population. Of about 20,000 patients each year who begin treatment for permanent kidney failure, about 8,000 are estimated to be suitable for transplantation.

It is widely believed by the transplant community today that a new era in organ transplantation is at hand. Survival of the transplanted cadaver kidney, which hovered around 50 percent one-year post-transplant for a long while, has improved in recent years. Early clinical trials on the use of Cyclosporin have achieved one-year post-transplant kidney survival rates of 80 percent. Patient survival has been in the 85 to 95 percent range, one year post-transplant for 5 years now, at least in the major transplant centers.

If a new era in transplantation is at hand, what factors deserve attention from a Congressional and Executive branch perspective? We recommend attention to the following:

Set Reasonable Objectives

We believe that a reasonable objective is to double the number of kidney transplant procedures over five years. This means an annual increment of 1,000 transplants, from a base of more than 5,000 in 1982, to over 10,000 in 1987. A level of 10,000 procedures annually would permit all new potential transplant recipients to receive a kidney and perhaps would allow a reduction in the existing pool of potential recipients.

Recognize the Complex Nature of Cost Savings

The cost savings of improved kidney transplantation, as analyzed in several recent studies, appear more modest than one might intuitively expect. Several factors influence this:

- Substantial front-end costs, associated with the transplant procedure and the organ procurement costs, dominate first-year cost profiles for the transplant patient. Thus, long-term cost savings to the ESRD Program from improved transplant outcomes will be obscured by limited short-term cost-savings.
- Important cost savings from improved transplantation have a relatively modest initial effect on the much larger dialysis portion of the ESRD Program. Cost savings for individual patients may be masked by the limited effects at the program level. But the savings are expected to be positive and to accumulate over time.

Cost effects are likely to occur within three areas:

- Transplant successes may become less expensive. Data from the University of Minnesota and the University of Pittsburgh suggest less initial hospitalization days and reduced frequency of readmissions. The potential for cost savings from these sources may vary substantially from transplant center to center, and may be offset somewhat from increased costs of medication.
- The costs of kidney transplantation failure may be expected to decline. Failure of a transplant results in death or a return to dialysis. In 1981, 3,425 individuals received a cadaver transplant, of whom approximately 3,000 were first transplants. Of these first transplant recipients, it is estimated that 10 percent died, 60 percent were alive with a functioning kidney at one-year post-transplant, and 30 percent returned to dialysis. If transplant failure occurs, and an individual returns to dialysis, the cost to HCFA of unsuccessfully treating rejection is approximately $3,500, the cost of removing the failed kidney when necessary is approximately $10,000, and the subsequent dialysis costs are on the average up to $3,000 more per year than the average dialysis patient. Savings

from reduced costs of failure, it should be emphasized, will become available from doing better at transplantation and are not contingent upon an increased supply of kidneys.

- The rate of growth of ESRD Program costs will decrease over time as patients are successfully shifted from dialysis to transplantation.

Mr. Chairman, the detailed analysis supporting these conclusions is now being completed and will be submitted for inclusion in the hearing record. Several general comments, however, deserve highlighting. First, the ESRD Program will remain primarily a dialysis program -- a large, relative successful but expensive treatment for permanent kidney failure -- even with improved outcomes of kidney transplantation. But improved transplantation results, in addition to the medical benefits they bring, can be expected to result in cost savings to the U.S. Government and to the nation, savings which will accumulate over time.

Improve Organ Procurement

What strategies can be pursued to increase the number of cadaver kidneys retrieved and used? First, the interaction of organ procurement teams with source hospitals can be increased in a systematic way. The most widely known "system" is the Centers for Disease Control (CDC) methodology, however modified, developed in the late 1970s.

Second, the efficiency of use of retrieved kidneys deserves careful analysis. Currently, 20 to 25 percent of retrieved kidneys are not used for a variety of reasons. Attention needs to be focused on the prospects for increasing the ratio of kidneys used to those retrieved.

Third, the CDC experience in the late 1970s deserves reevaluation. Practically all interpretations of this experience point to the benefits of using the CDC methodology, or of systematizing the procurement process, in increasing the number of retrieved kidneys. Overlooked has been the fact that the CDC experience involved increasing the procurement resources expended in two areas of the country. Given the successful CDC effect, a reasonable inference is that increased investment in procurement may also result in increased numbers of kidneys retrieved. If so, reimbursing procurement on the basis of the current cost of each retrieved kidney may limit the capacity of organ procurement teams and thus limit the volume of retrieved kidneys.

Fourth, if the results of transplantation improve, the country should take advantage of this through public education that disseminates widely the information about this improvement. Altruistic behavior in the form of voluntary donation of kidneys may relate to the perception of the probability of a successful outcome from transplantation. A recent Gallup Poll showed, for a national sample of 1,488 individuals, that 49 percent believed that the donation of a kidney "can extend that person's life substantially" but that 42 percent expressed uncertainty--

receiving a kidney "might or might not extend that persons life." Of those who expressed least uncertainty about the benefit, 60 percent expressed the willingness to permit the donation of their own kidneys; for those indicating greater uncertainty about the effects of transplantation, however, only 36 percent expressed willingness to donate their own kidneys.

It might reasonably be expected, therefore that if outcomes improve, and the perception of improved outcomes increase, that a corresponding increase in willingness to donate will occur. It might further be expected, then, that a shift in attitudes-intentions-behavior will occur that will result in increased organ donations. Many qualifications are interspersed in this line of reasoning, but the argument basically assumes that altruistic behavior is related to the perceived likelihood that donated kidneys will successfully prolong life. Public policy should emphasize this and not prematurely deem altruism a failure.

Fifth, and a corollary to the above, presumed consent laws should not receive high priority. We believe important ethical and social policy issues are at stake in this issue and these deserve thorough public discussion and debate. These issues notwithstanding, and simply as a practical matter,it is reasonable to assume that it will require a decade or more to enact such laws in the fifty states. It was in 1970, after all, that Kansas adopted the first brain death statute. Thirteen years later, approximately 30 states have done so, Illinois appears on the threshhold of doing so and New York has not done so. A long, complex social process is required to introduce such a major change in the legal regime govering organ donation. Immediate energies can better be devoted to the improved performance of the existing system.

Policy Implications

If a new era in transplantation as a treatment for end-stage renal disease is at hand, what specific policy issues require attention. At lease five suggest themself:

- Congress should examine the issue of reimbursing immuno-suppressive drugs usedly transplant recipients for "outpatient services."
- Congress should eliminate the three year limit on eligibility for benefits of successful transplant recipients.
- Congress and the Executive Branch should examine the propositon that increased resouces invested in organ procurement might well yield higher numbers of retreived kidneys.
- Congress and the Executive branch should recognize that the capability of the federal government to administer the End-Stage Renal Disease Program is so weak that they should search for ways to promote learning within the the administratively decentralized, geographically dispersed organ procurement and kidney transplant system.
- Finally, Congress and the Executive branch should acknowledge that the institutional mechanism for assessing the nature and implications of new developments like improved immuno-suppressive drugs are so weak that they demand reevaluation.

I hope these remarks help your deliberations on this subject of organ procurement and transplantation.

Mr. **Gore**. Well, they surely do, and we will have some questions. We will have two more witnesses first.

We have a vote on the floor, so with your indulgence, we will recess for approximately 10 minutes, and then we will come back in and finish the hearing.

[Short recess taken.]

Mr. **Gore**. The subcommittee will come back to order.

Our next witness is Dr. Jeffrey Prottas, visiting professor at the Center for Health Policy Analysis and Research, Florence Heller Graduate School, Brandeis University.

Dr. Prottas, am I pronouncing your name correctly?

Mr. **Prottas**. You are.

Mr. **Gore**. Good. I am doing well today.

Without objection, we have already put your statement in the record. If you care to summarize your statement, we would appreciate it because we are running short on time, but we are delighted to have you here, and we look forward to hearing your testimony, so please proceed.

STATEMENT OF DR. JEFFREY M. PROTTAS, VISITING PROFESSOR, CENTER FOR HEALTH POLICY ANALYSIS AND RESEARCH, FLORENCE HELLER GRADUATE SCHOOL, BRANDEIS UNIVERSITY

Dr. **Prottas**. I will summarize the key points of my testimony.

First of all, I would like to say the testimony is based on more than 3 years of research into the end-stage renal disease program. The last 2 years of that research have been an evaluation of the Nation's organ procurement system.

In the course of that research, which is almost completed, I will have visited or surveyed every organ procurement agency in the country and analyzed the financial statements of each agency. This research has been funded by HCFA.

The work originated in part in HCFA's appreciation of the fact that there is a chronic shortage of cadaveric organs for transplantation. The goal of the research, therefore, has been to recommend reforms in the organ procurement system so as to increase the number of organs obtained each year.

A secondary goal has been to identify cost-effective approaches to organ procurement.

The Nation's organ procurement system consists of approximately 120 OPA's—that is, organ procurement agencies. Thirty-four of these are independent agencies, not part of a transplant hospital. The remaining 85 or so are hospital-based agencies.

There is very great variation among OPA's in terms of size and effectiveness. On average, the independent agencies are larger and more effective than the hospital-based agencies. Although they represent only 25 percent of the OPA's, they procure more than 50 percent of the kidneys.

In 1981, 4,435 cadaveric kidneys were procured for transplant purposes. It is certain that our organ procurement system needs to be improved because it does not in fact meet our needs. However, I think it is very important for the committee not to lose sight of the fact that the system actually works quite well. It is, without a doubt, the most extensive and effective organ procurement system in the world.

It also could be a very much better system. We know it could be a better system because some parts of it are already very much better. The best of the independent agencies retrieve twice as many kidneys per capita as does the system as a whole. Therefore, I think, without changing the present law and without changing our present basic approach to organ procurement, we could double the number of kidneys procured each year in the United States.

To bring this about, I think we need to make three basic kinds of changes. We need to regionalize the organ procurement system. At present, the coverage of the country is extremely uneven in terms of organ procurement. There is one agency that covers virtually all of New England, another agency that covers virtually all of southern California, and both do very well. On the other hand, there are four procurement agencies in North Carolina; there are four agencies in Washington, D.C., here; there are five and perhaps six agencies operating out of Chicago.

The result of this is that, in many cases, OPA's are simply too small to do the job well. In some cases, they do not even have one full-time employee. In many instances, OPA's find themselves in competition for access to hospitals. In many of the same cases, there is a very uneconomical replication of facilities. I think all of these things need to be dealt with.

Therefore, I would recommend that the Government either encourage or enforce a regionalization program. I want to make it clear that I am not speaking of half a dozen agencies or even a dozen agencies. Organ procurement needs to be done on the local level. We probably need 30 or even 40 organ procurement agencies, but we certainly do not need 120 agencies in the Nation.

A second important change is to increase the national oversight and accountability. The independent agencies are presently all overseen by a single intermediary. That intermediary has full-time employees and their task is relatively easy because those agencies do nothing but organ procurement.

Hospital-based agencies are a very different matter. They are a very small part of most hospitals. It is very difficult to tell exactly what the organ procurement staff is doing. In addition, organ procurement is such a very small part of what HCFA does that there is nobody in HCFA who has responsibility to oversee these programs.

It is probably true that at the beginning of the program, this lack of Government oversight was not a bad idea. It was a kind of benign neglect while the program was first developing and everybody was seeking methods of operation. But I think we are past that stage, and we need a lot more national direction.

There are two kinds of options. One is simply to encourage HCFA to provide that kind of oversight. I don't want to underestimate the difficulty of that. There are 85 agencies, they are spread across the country, and, most difficultly, they are embedded in very large hospitals. So it is very hard to oversee what they do.

Another alternative solution is to encourage the development of the independent agencies. There are three advantages, I think, to doing that. The first is, in general, independent agencies have a better track record for effectiveness. They obtain more kidneys per population.

Second, they are increasing on their on. When I began the study 2 years, there were 21 such agencies; now there are 34. So, for a variety of reasons, many people in organ procurement already see the advantages of an independent agency.

And, third, they are very much easier to watch because they do nothing but organ procurement.

However, I want to modify this recommendation a bit because my research has not yet been completed, and until the data is in on exactly how the hospital-based agencies work as a whole, I am not sure I want to go quite too far. I think the spread of independent agency is a probable outcome, but it is certainly not certain.

Also, there needs to be at least a certain degree of flexibility because organ procurement needs to be done on the local level, and therefore you need to have some flexibility as to what structures suit local needs. But in any case, we definitely need more oversight, and I think that is one method of obtaining it.

The third step that is necessary if we are going to obtain a significant increase in the number of organs is to increase the operational effectiveness of individual OPA's. The key elements in that are that the OPA's must obtain a functional independence from transplant teams and transplant hospitals, and they must undertake to actively intervene in community hospitals where the potential donors are to be found.

Success at organ procurement requires the cooperation of those who have access to potential donors. This primarily means nontransplant hospitals and critical care personnel—nurses and neurosurgeons or neurologists. It secondarily means families of donors.

Therefore, OPA's are essentially marketing activities or sales activities whose clientele are not transplant surgeons and not transplant hospitals but community hospitals and those people working in community hospitals. So that re-orientation needs to be made.

In my written testimony and in my preliminary report to HCFA, I have detailed the kinds of managerial strategies that would lead to this orientation, but as that required 95 pages, I will not go into it in detail now.

I think it suffices to say here that in order to obtain those results, first of all, the agencies must be above a minimal size. A very small agency simply does not have the manpower or the status to be able to obtain that kind of independence.

Second, except when exceptional personalities involved, it requires that the organ procurement effort be somewhat insulated from the daily direction of physicians clinically involved in transplantation.

These three changes taken together could double the number of organs—kidneys—procured each year in the United States. It is important, however, to keep in mind the fact that the number of organs we retrieve is not the number of organs that we transplant. In 1981, 23 percent of the organs retrieved were not transplanted. Some of that wastage is medically unavoidable. But the fact that some OPA's have a wastage rate of less than 10 percent indicates to me that a lot of it is avoidable. I don't know how to avoid it, but

I think that we ought to know, and someone ought to be looking into that, because that is a terrible waste.

In passing, I would like to emphasize the fact that I don't think that that wastage rate represents a failure of our organ sharing system. The UNOS computer registry, which is a registry of recipients, is an absolutely basic element in the success of the Nation's organ procurement system. By and large, it seems to me that it works quite well.

In my written testimony, I next discuss a number of alternatives to our present system, and I will not go into those now, although if the committee wants to ask questions, I will be glad to talk about that.

I would only like to emphasize two points there. First of all, I consider that most of those recommendations are premature. Perhaps all of them are premature. I consider that some of them are very dangerous to organ procurement. We have a system that works now, and I am very leery of tinkering with it without considerable care.

The last point I would like to make is about the challenges facing the organ procurement system in the immediate future. The first challenge is one of scale. The technical advances that we have heard so much about in organ procurement are very likely to cause a very large increase in the demand for organs, and the system has to be ready to deal with that.

The second challenge lies in the area of non-renal organs. It is very important for the Committee, when trying to make policy on the issue of non-renal organs, to keep in mind certain facts about the present relationship between the organ procurement system and the procurement of non-renal organs.

The first point is that there is no choice at all. The present system is the way non-renal organs will be procured. It is a national system covering the whole country with hundreds of people working for it, and that is the way we will procure those organs.

Second, we are already doing that. We have been procuring eyes routinely in almost all organ procurement agencies, and in many cases skin and bones as well have been procured on a routine basis.

Essentially, these organs have piggybacked on kidneys, and nobody has concerned himself very much about the issue of cost. The organ procurement system is also the way we are now procuring livers and hearts, and although costs have been considered in this area, the issue of cost has not been thought through completely. I think, we are approaching the time when it needs to be thought through completely.

As the number of non-renal organs increases, it will be necessary to devise a policy defining the relationship between kidney procurement and the procurement of non-renal organs. It will be necessary to decide who pays for those organs, what exactly will they pay, and under what rules.

I think it is very important for the committee, when devising that policy, to consider what that policy will do to the present organ procurement system. In my judgment, right now, very few organ procurement agencies could adequately deal with the very complex system of multiple payers, multiple rules, and multiple distribution systems. Any policy that does not take into account the demands it places on our present organ procurement system is likely to have some very detrimental effects.

In conclusion, I would like to say that we already have a very successful organ procurement system and that all policy changes that we consider ought to build on that system's strengths, and changes in that system ought to be undertaken only with the greatest care.

Thank you.

[The prepared statement of Dr. Prottas follows:]

TESTIMONY BY JEFFREY M. PROTTAS, HEALTH POLICY CENTER, BRANDEIS UNIVERSITY

OBTAINING REPLACEMENTS: THE ORGANIZATIONAL FRAMEWORK OF ORGAN PROCUREMENT*

Change begets change and technical change often begets complimentary organizational innovation. The process is not, of course, inevitable nor is it inevitably successful when it does occur[1]. Nevertheless one of the most interesting and important public implications of tehcnical innovation is the adaptation of implementing organizations to new demands. This phenomenon has been observed for innovations ranging from computers[2] to transit vehicles[3]. A little noted but gratifyingly successful analogous process is presently underway in the field of organ, more particularly, kidney procurement. In the last decade our capacity, both technical and social, for replacing a nonfunctioning human organ with another functional one has increased significantly. For a number of reasons the human kidney has led this process and there is now a large demand for transplantable kidneys. In response to this need there has grown an entirely new type of organization -- an "organ procurement agency" (OPA) whose task it is to locate and obtain human organs for transplantation. Indeed, under the dual impetus of medical capability and government financing, there has grown an organ procurement system, complex in organization and nation-wide in scope. This article will discuss this procurement system, its sources, organzation, scale and the nature of its "core technology," i.e., the organizational tasks essential to its success.

Technical and Social Basis of Organ Procurement

The need for organ procurement agencies is a function of the need for human organs for transplantation purposes. This need, in turn, is a function of the interaction of medical/technical advances, the prevalence of relevant illnesses and the availability of the resources necessary to finance transplantation. All of these have come together over the last decade.

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*Based in part on an article published in the Journal of Health Politics, Policy and Law in the Summer of 1983.

There are a number of medical problems that must be resolved for any sort of transplantation procedure to become clinically acceptable. Perfection of surgical techniques and the development of immunosuppressant drugs are the most critical and obvious. By themselves, however, they are insufficient. The success of kidney transplantation, in terms of the numbers done, demonstrates that some method must also be developed to permit the maintenance of potential recipients in reasonable health while a suitable organ is being located. Therefore, the development of the dialysis machine and the vascular shunt have great importance in explaining the technical underpinnings of the demand for replacement kidneys[4]. These two medical developments, the first a mechanism for filtering blood, the second a method of repeatedly obtaining access to a patient's circulatory system, have permitted the development of hemodialysis. Although there are other methods of dialyzing blood (cleansing it of impurities) hemodialysis remains the predominate treatment for permanent kidney failure. Patients on hemodialysis receive three 3 to 5 hour treatments per week. These treatments involve pumping blood through a filtration system. It is the existence of this non-surgical treatment that sets the medical stage for the vast demand for human kidneys; the absence of a comparable treatment for heart and liver failure has so far precluded any comparable demand for those organs. On the other hand drug treatment of diabetes may be comparable to dialysis in its contribution to supporting a large demand for pancreas transplants.

Fifty-eight thousand Americans are now being treated by some form of dialysis. This represents almost the total potential need for a replacement for nonfunctional kidneys. (In fact there may be another 5 or 6 thousand Americans with chronic kidney failure; the 58,000 figure only includes those covered by the Social Security system. It is estimated that 10% of the U.S. population is not so covered[5].) Not all of those on dialysis are candidates for a transplant, most can be excluded for medical reasons. Nevertheless, there are approximately 7,500 Americans on formal recipient registers awaiting a kidney. Despite a slow increase in the number of transplants done each year, this list has shown no sign of diminution. As about 3,400 cadaveric transplants were done in 1982, there is clearly a great excess of demand for, over supply of, replacement kidneys.

Indeed preliminary work done at the University of Toronto implies that there may be a substantial reserve demand not listed in registries[6]. Some have estimated this demand is in excess of 22,000[7]. The AMA's Council on Scientific Affairs sets it even higher. They believe that half of those on long-term dialysis may be potential candidates for a transplant. In their view the desirability of that option will, in the next few years, be enhanced by advances in the "control of the rejection mechanism."[8] Indeed one such advance, an immunosuppressant drug called cyclosporin will probably enter regular clinical use this summer. Many of the transplant surgeons I have interviewed believe this drug will have a substantill effect on kidney graft survival and an even more significant effect on graft survival rates for non-renal organs. We must therefore anticipate a large increase in the demand for transplantable organs, both renal and non-renal, in the near future.

In some sense the underlying human demand for a transplantable kidney (or any other organ) is independent of technical/medical factors. It reflects the frequency of kidney failure and the medical characteristics of its sufferers--which defines how many victims are candidates for transplant surgery. In practice the actual demand for transplantable kidneys represents some interaction between technical and human factors. The inadequacy of early estimates of the potential demand for dialysis and the continuous growth of the dialysis population both illustrate this interaction effect.

In 1963, the Artificial Kidney Center in Seattle, the center of pioneer work in dialysis, estimated that there were 5 to 20 "ideal" candidates per million for dialysis in the State of Washington[9]. In 1967, the Gottschalk report estimated that there were only 4,000-5,000 new potential dialysis patients each year in the United States[10]! Even as late as 1972, median estimates of 7,500 suitable patients was considered sound[11]; yet, in 1981, 21,535 patients started dialysis for the first time[11]. Since kidney failure is 100% fatal if untreated these estimates provide a striking example of the interaction between the demand for and the availability of a medical service. This should be kept in mind when considering the probable demand for other organ transplants.

But, as Braudel points out "...No innovation has any value except in relation to the social pressure that maintains and imposes it."[13] In this case neither the prevalence of kidney failure, nor the availability of techniques to treat it, generated a serious demand for transplantable kidneys until the U.S. Congress was prevailed upon to bear the cost of all forms of treatment for permanent kidney failure. Congress' reason for doing so are complex and need not concern us[14], but the step itself was critical because dialysis and kidney transplants are both extremely expensive and beyond the means of almost all Americans. In 1972, the Congress passed the End-Stage Renal Disease Program (PL 92-603) by which it undertook to cover, under the Social Security system, all victims of permanent kidney failure. In 1967, there were 1,000 patients on dialysis in the United States. In 1973, there were 11,000 patients and last year (1982) an estimated 58,500[15].

While the growth in the number of transplants has been much slower, they too are clearly the result of this social decision to publicly support the cost of treatment for kidney failure. Indeed it has been from the first the official policy of the government to favor transplantation as a treatment modality.

All these factors, technical, human and social, have worked together to generate a need for human kidneys and this, in turn has brought into existence organizations dedicated to fulfilling that need. (These organizations too are supported by public funds under the End-Stage Renal Disease (ESRD) program.))

In 1982 approximately 4,400 cadaveric kidneys were obtained in the United States. Of these perhaps 3,400 were in fact transplanted, representing 70% of the organs transplanted that year. (The remainder were obtained from a living relative of the recipient.) This represents only a small percentage of the total number of organs theoretically available. Obviously estimating the number of deaths that might have resulted in producing organs suitable for transplantation is very difficult and such a figure must be treated with reserve. Nevertheless it has been estimated that some 50,000 transplantable kidneys become potentially available each year.[15] Even if more conservative estimates are used it is clear that the number of potentially usable kidneys does not represent a limitation of the ability of organ procurement agencies to meet the demand. On the contrary, the limiting factor in kidney supply lies in the organizational ability to locate and obtain organs.

The Organ Procurement Process

From an organizational point of view organ procurement is a complex and difficult task. Success requires the cooperation of many actors not in the procurement agency itself--neuro-surgeons, nurses, families, other procurement agencies, tissue typing laboratories and transplant surgeons. Each and any of these people can, by acts of commission or omission, cause the procurement to fail. It is the Procurement Agency's task to motivate all of them to cooperate and to structure the situation so that they can do so in ways consistent with their primary responsibilities. In addition the Agency must coordinate the activities of each and complete other tasks assigned to it.

The actual sequence of organ procurement differs from agency to agency and, indeed, from donor to donor, however, the basic elements are always the same. The first step is a telephone referral. Usually an Intensive Care Unit (ICU) nurse calls to say that they have a potential donor. (Most donors die in such units; for medical and organizational reasons very few die in emergency rooms.) The suitability of the donor is determined in a preliminary fashion either over the phone or later at the hospital. Donor maintenance steps may be necessary—maintaining fluid balance for example. At this point the patient is still alive so, of course, no steps inconsistent with treatment are taken. However, contact is not undertaken until it is clear that the patient is dying. In some cases a representative of the Agency will go into the ICU to be on hand when the patient dies. This varies by policy, timing and geography. Once a patient has died a neuro-surgeon must be obtained to declare brain death and the family must be notified. Most Agencies prefer the physician or the nurse to have prepared the family for the possibility of donation earlier, during the time they were preparing the family for the imminent death of their relative.

Once the patient has been declared brain dead the family must be approached for permission to remove the kidneys. Although every state has passed the Uniform Anatomical Gift Act which permits a "will" authorizing organ removal, hospitals will generally not remove organs without family permission. Once approval is obtained steps are taken to maintain the viability of the donor's kidneys and blood may be taken for preliminary typing. The Agency must then arrange for an operating room and a removal team. The kidneys must be removed under sterile conditions and by a physician. In many cases an Agency will also try to obtain permission to remove other organs. Most do this almost routinely for eyes and on special request for bone, skin, heart or liver. If permission is obtained the relevant agency is contacted to come and remove "their" organ.

Once the kidney is removed the agency has complete responsibility for it. It must be evaluated and preserved. Preservation is done by one of two methods. Either the kidney is packed in ice, or it is placed in a special "perfusion machine" designed exclusively for kidney preservation.

Tissue samples are sent to a histocompatability laboratory. Tissue typing may take from 4 to 10 hours. Once the immunological characteristics of the donated kidney are known the search for a suitable recipient can begin. All OPAs first search the list of transplantation centers in their catchment area. Decision criteria for what constitutes an acceptable match vary and are in the hands of a medical board or the transplant surgeon.

If no local recipient is suitable the Agency attempts to export the kidney. All those east of the Rocky Mountains employ the UNOS (United Network for Organ Sharing) list of transplant recipients to locate a potential recipient. Each Agency uses somewhat different techniques for choosing which organ procurement agency to call about a kidney. The first test is generally the apparent quality of histocompatability match between the kidney and the recipient. However, other factors often come in. Location is one--close transplant centers are preferred as transportation cost and time is minimized. But the existence of alternative potential recipients is also a factor. It is not possible to be sure that any given recipient will actually test negative with any specific kidney, therefore, sending a kidney is always a risk. If the first patient's blood reacts to the offered kidney it is necessary to find a substitute, for this reason, a transplant center with alternative possible recipients is preferred. The procuring agency has the responsibility of physically transporting the kidney. Once the kidney is placed with a local transplant surgeon or sent to another center, the job of the procurement agency is over. Naturally, an OPA will be on the other end of the organ sharing process in which case once the kidney has been accepted by them and is delivered it is tested against potential recipients locally. If no match is found the OPA will then usually try to re-export the kidney. Those in organ procurement have a very strong commitment to using every kidney available.

All this must be done at unpredictable intervals and within a very short period of time. The location of a potential donor and the timing of his availability are unpredictable. In some cases weeks, even months, can go by without a single donor; at other times two, three or four donors may be available simultaneously. The process of donation must be completed quickly. Potential donors are typically not in the hospital long before death and while a brain-dead donor can be maintained for some time before it becomes essential to remove the kidneys, it is medically risky to delay and socially difficult. Once a family has consented to donation they are understandably anxious to have the process finished immediately.

Even after excision there is time pressure. A kidney out of the body over 24 hours becomes increasingly difficult to place with a transplant team.

A survey of 35 transplant centers indicates that 25 of them will not use a kidney that was removed more than 50 hours before (30 hours if a less costly preservation system is used). This 30 or 50 hours must include transportation and tissue typing time. Time pressures are present throughout the procurement process.

Of course, the original steps needed to procure kidneys start before the death of any potential donor. A procurement agency must first decide which hospitals ought to be asked to refer appropriate patients to the program. This is a strategic decision of the first importance. Not all hospitals are equally useful in this role. At a minimum a referral hospital must have an emergency service (85% of donors die as a result of accidents) and a neurosurgeon (or a neurologist) to declare brain death. (In practice only a patient whose heart is still beating is of use as a donor, this obviously requires that he or she be declared dead using brain death criteria.) Beyond these requirements a number of delicate balances must be struck. Each agency only has limited resources and experience has shown that most hospitals have to be in frequent contact with the Agency if they are to routinely refer donors. A smaller number of hospitals makes effective contact possible; a larger number increases the coverage of the potential donor pool. The kind of hospital is also an issue, large city hospitals see the most trauma but are not always the most cooperative, smaller outlying hospitals have fewer potential donors and are harder to cover (because they are geographically dispersed) but are often willing to be involved. Finally, the issue of how much contact is appropriate must be resolved. Excessive contact is both wasteful and may antagonize critical personnel; too little contact and the staff tends to forget to be watchful for opportunities.

Once a hospital has agreed to participate, the cooperation of critical staff must be obtained. These are the neuro-surgeons, or less commonly, the neurologists, and the intensive care nursing staff.

The cooperation of the neuro-surgeon is necessary as almost all potential donors are his patients. He therefore has formal responsibility for them and must give permission for the organ procurement agency to be contacted regarding them. In addition, he must declare the patient brain dead and so inform the family before any donation related activities can take place.

The intensive care, often the neuro-intensive care, nursing staff are also critical. Most of the in-hospital burden of organ procurement falls on them. They usually must actually contact the agency. They care for the dying patient and must monitor his condition and perhaps take steps to protect his kidneys. They often have the most dealings with the donor's family. Indeed it is generally they who take the active role with the physician merely acquiescing.

One of the primary responsibilities of a procurement agency is to motivate these people. Unless the nursing staff and the physician cooperate the agency will not even be informed that a potential donor exists. This responsibility is discharged via some form of "professional education." This ill-named activity absorbs a substantial part of the time of OPAs. It may take any of a number of forms, from periodic visits to intensive care units (ICUs) simply to maintain contact with nurses, to yearly meetings with all the trappings of professional association gatherings. A major issue in organ procurement is how "professional education" ought to be done. In any case this, unlike hospital selection and contact, is not a single act but a major ongoing responsibility. Motivation must be continually reinforced.

A separate activity undertaken by many OPAs is public education. Strictly speaking this is not part of the organ procurement process but is meant to facilitate that process by increasing public awareness of and support for organ donation. The ultimate goal of public education in this area is to increase the probability that a potential donor's family will grant permission to excise the kidneys. Procurement agencies vary greatly in their commitment to public education and there is controversy over its effectiveness and appropriateness[17].

The Organ Procurement System

As difficult as these organizational tasks may be, there is a large network of organizations involved in completing them. Nation-wide there are approximately 152 transplantation hospitals in th United States[18]; with few exceptions each of these is involved through some organizational arrangement in kidney procurement. About 85% of these hospitals run their own organ procurement agency, the remainder depend on one of the 32 active "Independent Organ Procurement Agencies." (There are 2 other such Agencies that don't actually procure kidneys). All organ procurement agencies (OPAs) have certain things in common. All are non-profit agencies, either directly incorporated as such or operating as a division of a hospital. All are funded by the same End-Stage Renal Disease Program that pays for dialysis treatments. However, unlike all other aspects of the ESRD Program the government pays 100% of "kidney aquisition costs", as opposed to 80% of costs covered for all other medical expenses. In this sense OPAs are "fiscal drops"[19], i.e. they are solely dependent on the government for financing and they operate solely to further a specific governmental goal but they are not governmental agencies in a legal sense. They are a public-private hybrid that would be termed "strange" were they not so common.

The Independent Organ Procurement Agencies (IOPAs) differ in a number of ways from hospital based Agencies and are important out of proportion to their number. The formal distinction lies in the fact that they are not part of any direct medical delivery organization but are separately incorporated non-profit organizations. But more important than the formal organizational differences are the differences in size and effectiveness. On average the IOPAs are larger, more effective and more innovative than are the hospital-based Agencies--although, of course, exceptions to this generalization can be found among the over 80 hospital-based Agencies.

Many of the IOPAs are regional in scope. For example one IOPA draws organs from all of New England, two share almost all of Texas between them, two others share Pennsylvania, and overlap into New Jersey, Ohio and West Virginia. Although IOPAs represent only some 18% of the nation's procurement agencies, they actually obtain over 40% of the nation's transplantable kidneys. This disproportionate success reflects more than simply larger catchment areas; IOPAs are, on average, more effective than hospital-based agencies.

The Atlanta based Center for Disease Control has undertaken a number of retrospective record reviews in hospitals to estimate the number of potential kidney donors as a percentage of all in-hospital deaths[20]. While the resultant figures are merely estimates and can be expected to vary over time and across locations they do provide a yard-stick against which to measure organ procurement agency success. If the entire nation were serviced by procurement agencies as effective as the IOPAs, a 50% increase in the number of kidneys procured could be expected. If it were covered by OPAs as effective as the most effective IOPAs, the number of organs retrieved would be doubled[21]!

Perhaps this effectiveness is part of the reason for the rapid growth in the numbers of IOPAs in the last year. At the end of 1980 there were 21 organizations designated as IOPAs, by the summer of 1982 there were 34. The importance of the IOPAs to the organ procurement system is not only large but growing. This is not to say that one finds a high degree of uniformity among IOPAs either in scale or effectiveness. Their explosive growth alone would preclude this. Some have yet to obtain their first kidney, and some have retrieved many hundreds over the years. Some directly serve more than half a dozen transplant hospitals, some only one. The largest had a budget of 1.5 million dollars in 1980, the smallest (in the program at that time) has a budget of only $33,280! There is also a great deal of organizational variation to be found; some IOPAs grew out of local Kidney Foundations and retain those ties, others eschew any relationship with the Kidney Foundation; some are under the direction of the entrepreneurial physicians who founded them, in others the medical presence is all but invisible in daily operations. Add to this the regional, operational and even philosophical differences and the IOPAs are a heterogeneous group. In the next section we will condiser what shared characteristics can explain their apparent successes in organ procurement.

Variations among the hospital-based agencies is, of course, even greater. Some are procurement agencies only in name, having no full-time staff and procuring few if any organs, others operate full-fledged procurement agencies with national reputations. Unfortunately detailed data on the variations among hospital based procurement agencies is not presently available. The author is presently engaged in gathering such data.

Despite the differences between and within the two types of organ procurement agencies the nation does have a reasonably integrated organ procurement effort. This is demonstrated by the dependence of organ procurement agencies on the inter-agency exchange of kidneys. Again good data is available only for the IOPAs, but it shows that approximately 37% of the kidneys procured by IOPAs are exported by those Agencies to some transplantation hospital outside of their catchment area. A marginally smaller number are imported into by IOPAs from other centers. This means that almost 40% of all kidneys transplanted in hospitals associated with IOPAs do not originate in the region where the transplant takes place. As individual IOPAs are, on average, more than twice the size of hospital-based agencies this percentage is presumably far greater among hospitals with their own procurement effort. (Among transplant hospitals in Washington, D.C., 60-80% of the transplanted kidneys were obtained by an OPA other than the hospital's own.)

This extensive inter-agency flow of organs is possible only because the United Network for Organ Sharing (UNOS) provides a continually up-dated computer print-out of all patients awaiting a transplant at any transplant center east of the Rocky Mountains and most of those on the West Coast as well. The UNOS listing displays potential recipients categorized by histocompatability characteristics and so permits a simple search for potential recipients.

The search is almost nation-wide because not all of the West Coast agencies list with the UNOS system. In addition, there are certain regional and "network" biases in inter-agency organ sharing. The regional effects are largely the result of time constraints--kidneys cannot be maintained outside of a human body very long and so there are strong reasons to ship them to an accessible location. This also gives Agencies located at major air centers an advantage and has caused some of the less accessible Agencies to purchase airplanes. The "network" effect reflects the uncertainties of histocompatiability matching and organ removal and preservation. Sharing an organ involves both parties in an act of trust--the receiver must trust the competence of the providing agency and the provider must trust the receiver to find a suitable recipient if the best one listed on the computer doesn't prove suitable. Larger agencies and those that import and export frequently develop the contacts and trust and will therefore be preferred partners. Beyond these caveats, however, the inter-dependency of procurement agencies is substantial and makes it sensible to see them as part of a single national system rather than as 120 purely local efforts.

Marketing and the Success of the IOPAs

The greater success of Independent Organ Procurement Agencies can, in large part, be attributed to their greater willingness and capacity to see their "clientele" as the staffs of non-transplant hospitals, and to aggressively market organ procurement to that clientele. Historically, this is not the orientation of organ procurement.

In most locations organ procurement efforts began as ad hoc activities of involved physicians. These physicians employed their personal medical contacts in their own and nearby hospitals to obtain assistance and referrals. The basic motif of these activities was personal assistance to help supply the raw material for the physician's work, or, more generously, to aid the physician in the care of his patients. In most instances, formal organ procurement agencies evolved when the physicians found the burden of work too onerous and the yield of organs too small.

Organizationally, hospital-based procurement agencies remain extensions of the transplant surgeon's or nephrologists' reach--they are structurally ancillary to the transplantation team. Nor have all IOPAs outgrown this orientation, in some the medical director's daily involvement enforces, informally, the dominance of the direct medical service delivery orientation. Nevertheless IOPAs as a group have moved, to varying degrees, away from this definition of their role and therein lies the ground of their success.

The final goal of organ procurement is, of course, to provide a transplantation team with the organs they need; but the basic task of an organ procurement agency is to mobilize and maintain support for organ procurement from those individuals and institutions that control suitable cadavers. Within the transplantation hospital it may be possible (but often is not) to use the power of the transplantation service to obtain cooperation from the critical care units that control potential donors. Outside of the transplantation hospital cooperation can only be obtained by manipulation. The sine qua non of successful organ procurement is salesmanship.

There are three gorups that control an organ procurement agency's access to human organs, two are medical professionals in non-transplant hospitals, neuro-surgeons and intensive care nurses, and the third is the family of the potential donor. These represent the critical environment of the Agency, not transplant surgeons and these must be "sold" on organ donation if the Agency is to be effective. IOPAs, organizationally and operationally more distant from transplantation hospitals, have generally been more successful in recognizing and adapting to this reality. The growth of the inter-agency flow of kidneys has, of course, been a pre-condition for this change as a procurement agency no longer depends on a single team to take all its kidneys. Both psychologically and, to a lesser degree, practically, procurement Agencies no long "work for" a single team but serve the entire transplantation community.

The conceptualization of organ procurement as a medical marketing activity rather than a medical service activity has implications for the sorts of people hired by the Agencies, the role of medical training and expertise in the Agency and the strategies pursued by the Agency's management. In all of these areas IOPAs have made progress.

The "keys to the kingdom" are held, in organ procurement, by the nurses and neuro-surgeons (sometimes neurologists) in non-transplant hospitals. It is they who control access to donors by informing the Agency of suitable patients. Their assistance is entirely voluntary--it cannot, ethically or legally, be compensated in any significant manner. (Strictly, no one involved in transplantation can declare a patient brain dead; practically, it is undesirable for anyone responsible for the care of a potential donor to derive any personal benefit from the donation of his or her organs.) Organ procurement agencies are selling altruism.

Involvement in organ procurement is not costless to medical personnel, it has both time and psychological costs. The neuro-surgeon has to declare a patient brain dead--a more involved and touchier step than simply letting a heart stop. He must explicitly confront his failure to save a patient, indeed, often anticipate it, and he must deal with the grief of the patient's family while explaining brain death to them. The nurse's responsibilities also increase. She bears an even greater burden for dealing with and talking to the family. She too must anticipate the death of a patient and often treat the "patient" after death, or while awaiting its official declaration, in order to protect his or her kidneys. This is a difficult psychological shift from the single-minded dedication to saving life typical of intensive care units. Indeed, in practice, it is on the nurse that the primary responsibility falls for identifying potential donors and initiating the entire process.

To induce this kind of cooperation organ procurement agencies depend primarily on "transplantation" or "procurement" coordinators. Medical expertise is relevant to the success of these coordinators almost solely as it acts to legitimate them with the hospital staff. It is the universal observation of coordinators that the medical expertise demanded of their jobs can be learned quickly by any intelligent person. (The removal and preservation of the kidney is another matter and is, often, not part of the coordinator's job. Indeed the trend toward dividing these aspects of organ procurement is symptomatic of its journey from medical to marketing orientations.) Among IOPAs, from 30% to 100% of the coordinator's time is spent in some form of marketing to these critical people. (Excluding time spent preserving organs in those Agencies that continue to combine these functions.) These marketing efforts are primarily of three types: personal selling, known as "surveillance," group presentations, known as "professional education," and the organization of conferences and testimonials. All three are variants of classical marketing techniques.

There are controversies among IOPAs over the effectiveness and even appropriateness of some of these marketing techniques; however, a majority of IOPAs routinely use all three. Personal selling is used or approved of by 70% of IOPAs, it is the most controversial approach. Concretely, it consists of unscheduled periodic visits to critical care units of associated hospitals primarily aimed at maintaining an awareness of organ procurement among ICU nurses. Its efficacy depends on the development of a good personal relationship between the coordinator and the hospital's ICU nurses. The approach is, therefore, low key and supportive; quite consistent with modern "customer-problem" approaches[22] to salesmenship.

"Professional education" approaches are more formalized. They usually consist of "in-service" training classes for nurses. Their formal goals are indeed educational and they certainly contain information of a technical and organizational nature about organ procurement and transplantation. Like "surveillance", however, their implicit goal is exhoratory. Unlike surveillance they depend less on developing a personal relationship and more on the use of professional and heirarchical authority to validate the professional involvement of nurses in the program. The fact that these sessions are formally sanctioned by the hospital and are presented in a classroom format support the marketing message.

Organizing conferences and meetings is a widespread, although minor, aspect of most IOPA's marketing efforts. The professional content of the sessions reinforces the message that organ procurement is a professionally appropriate activity in which to be involved. The fact that the meetings are held in pleasant surroundings and that the costs are often subsidized by the Agency also promotes good will and a sense of solidarity among participants and the Agency. The soundness of this approach is attested to by widespread corporate practice.

Inducing the family of the potential donor to grant permission to remove the kidneys is the last step in the procurement process. It is also a most delicate process requiring, from the "salesperson," both sensitivity and dedication. Humanity and efficacy require that the bereaved family be approached with consideration and empathy. All coordinators interviewed were very concerned not to increase the grief of the potential donor's family. At the same time, no routinized "pitch" could convince a family to give permission. Success requires careful attention to the concerns of the particular family being approached--reasons for permitting donation are multi-faceted and complex and must be addressed. This is the most difficult kind of "selling." Independent Agencies are remarkably successful at this. Coordinators report permission rates of 60-80% among white families. Success among blacks is much lower[23].

Finally, IOPAs have a great advantage in flexibility over most hospital-based Agencies. A hospital-based Agency that wishes to take a marketing approach may find itself unable to choose its targets effectively. Depending on its particular circumstances it may find itself limited to working at a few pre-selected hospitals. If these are not fertile ground, because of patient make-up, attitudes of key personnel, etc., there is little that they can do. An IOPA, on the other hand, can pick and choose among hospitals in order to find the most responsive to its marketing efforts. Of course, in the highly politized atmosphere of many medical communities, the

IOPA's choices may not be completely unfettered but it would still have the advantage over a hospital-based program. Indeed, in some locations, the IOPA was founded because the rivalry among hospitals could only be contained by the introduction of a neutral outside party.

Conclusions and Recommendations

Like blood, human kidneys can neither be manufactured nor adequately substituted for. Like blood, the potential supply of kidneys is practically limitless. Like blood, the actual supply of kidneys is largely a function of the effectiveness of the organizational infrastructure designed to obtain it. Unlike blood, the demand for kidneys is limited, however, it is large and growing. It presently exceeds supply substantially and there is reason to believe that recent developments in innumospression drugs will further increase that disparity. The looming non-medical issue in the transplantation field is, therefore, whether the organ procurement system has the capacity to respond to increased calls for organs.

This is a question for public policy because the End-Stage Renal Disease Program has made the federal government the sole purchaser of human kidneys. It has financial implications for the ESRD program as transplants can be less expensive than dialysis. It has human implications because a successful transplant is both medically and socially superior to dialysis. Quality of life is far better.

The experience of the Independent Organ Procurement Agencies demonstrates that is is possible to greatly increase the number of kidneys retrieved in the United States under present laws. What is needed is an acceptance of organ procurement as an exercise in public service marketing aimed, primarily, at medical professionals who can refer potential donors and, secondarily, at the families of those donors. This requires both the psychological and operational liberation of organ procurement from direct medical service units. Independent Agencies have demonstrated that one way to obtain this is through structural separation of the procurement agency and the transplant hospital. It is too early to state categorically that structural separation is a necessary condition for the development of a marketing orientation in organ procurement. It is certainly not sufficient as some IOPAs are organizationally distinct from transplant hospitals but operationally tied to a medical service orientation. Organizational data on the hospital based programs is only now being gathered and their lesser average effectiveness may hide some alternative models for obtaining the necessary operational flexibility. The critical factors for success in organ procurement are the desire and capacity to orient the organization toward the suppliers of kidneys not the users; organizational independence is a means to that end not an end in itself. Whether there are other practical means remains to be determined.

One thing is already clear, it is possible to increase the available cadaveric kidneys by orgnizational means. This has two important implications. The first is obvious, this ought to be done and it is, at least in part, the Federal government's responsibility to do it. The second is perhaps less obvious. Altruism works. That it can be encouraged and fostered by sensible "marketing" in no way undermines this fact. The marketing efforts that have such a good effect on organ procurement merely increase the salience of the altruistic impulse in those involved and diminish the obstacles to its exercise[24].

There are reasons to value the centrality of altruism in organ donation. Titmus has presented the social and moral advantages of altruism in the context of blood donations. He argues that the right to act altruisticly is an important human right and that its exercise is morally and psychologically beneficial. He further argues that society benefits from the enhanced sense of community that flows from "gift relationships[25]."

It is not necessary to accept Titmus's agruement to see that efforts to increase our supply of transplantable organs ought to begin with improving the extensive organ procurement system we have already developed. If incremental improvements in our present approach can meet our needs, then more sweeping, and risky, changes can be avoided.

Substantial increases in our supply of cadaveric organs can be obtained by improving the effectiveness of the nation organ procurement systems without recourse to basic changes in the law or ending our reliance on altruism. Variations within the present system indicate that, if the entire nation were serviced by organ procurement agencies as effective as the most effective Independent Organ Procurement Agencies, it might be possible to almost double the supply of organs. Such an increase would require the Health Care Financing Administration to take steps to improve the system overall and would require a number of operational changes to occur in the organ procurement agencies themselves.

System-wide Reforms

Regionalization of Organ Procurement

The present organ procurement system has grown in response to local medical practices, preferences and politics. As a result, the distribution of

OPAs across the country is absurdly uneven: a single agency services almost all of New England, another almost all of Southern California; yet Washington, D.C. has four agencies, Chicago has six and Louisiana, four! It may be that some OPAs have grown too large to effectively service their catchment areas, but it is certain that many OPAs are too small to do so. Some hospital based programs do not, in practice, have a single full-time organ procurement coordinator; many have only one. For a task that requires twenty-four-hour-a-day availability, quick response to referrals and unrelenting efforts to insure the participation of hospitals, nurses and doctors, there are clearly critical economies of scale. Moreover when several agencies attempt to operate in the same area, no amount of cooperation (and in multi-agency areas cooperation is not always a reality) can avoid inefficiencies. There is often a duplication of preservation and laboratory facilities and each agency faces artificial constraints on its choices of community hospitals in which to work. (The duplication of certain kinds of facilities occurs even in some Independent Agencies because hospitals are unwilling to surrender control over certain kinds of tissue-matching and preservation labs. This also is a poor use of public money.) The Health Care Financing Administration ought to address itself to this problem and encourage, or enforce, a more uniform coverage of the nation via some regionalization program.

Oversight, Direction and Support

Organ procurement is only a small part of HCFA's total budget. This, combined with a recent organization that eliminated the Office of End-Stage Renal Disease, means that there is no one in the Administration with over-all responsibility for organ procurement. This has meant a virtually untrammeled independence for hospital-based agencies as well as a total lack of direction and support. (Independent Agencies are administered separately.) The smaller agencies especially could benefit from assistance from Washington in matters of law and effective procedure. The absence of oversight raises other kinds of problems. It appears probable (but the data is still very sketchy) that many hospital based programs fund activities under "kidney acquisition" that may not strictly belong under that rubric. Unlike all other reimbursements, organ procurement is reimbursed at 100% of cost. Hospitals are very complex organizations and activities closely related to organ procurement and transplantation such as research, immunology laboratories, transplant recipient work, etc., can easily shade into "kidney acquisition." This can be done without the least intent to act inappropriately but, without guidance and systematic oversight, it is inevitable that the ESRD program pay for activities that are not really organ procurement.

One possible solution to this is closer oversight of hospital based programs, another is to encourage the phasing out of hospital based programs in favor of Independent Agencies. The oversight issue alone would not justify such a step but, combined with the apparent superior effectiveness of Independent Agencies, such a policy might be considered. Because the research into hospital-based agencies is not completed, it is premature to urge such a solution. However, it ought to be added that the rapid growth in the number of Independent Agencies over the last year implies that the organ procurement community itself sees certain persuasive advantages to that form of organization.

Operational Reforms Within Organ Procurement Agencies

Motivating Medical Professionals

Obtaining the assistance of nurses and physicians in community hospitals is the most important element in successful organ procurement. For this reason, knowledge of variations in local attitudes and practices are of great importance and no single, rigid formula for success can be insisted upon. Nevertheless, certain kinds of activities have been shown to be effective in a variety of settings.

The utility of in-service training sessions as a motivational tool is more or less universally acknowledged and so doesn't need to be stressed. The effectiveness of "surveillance" is less widely accepted but is also great.

The Center for Disease Control has pioneered the use of surveillance in organ procurement. In their terminology, surveillance is "the continual process of identifying and reporting each potential donor soon enough to make retrieval possible."[26] While the CDC type of surveillance has proven effective, it is also very time-consuming and expensive. A more operationally applicable form of surveillance emphasizes the marketing goals of the organ procurement agencies and so is directed more toward maintaining the involvement of nurses than toward directly identifying potential donors. The type of surveillance I advocate involves regular but unscheduled visits to critical care units by organ procurement coordinators. The purpose of these visits is not to find a donor but to increase the saliency of organ procurement among the nursing (and perhaps physician) staff and to develop a personal relationship with the staff. The development of this kind of relationship is a critical component of many kinds of salesmenship and can be very effecacious. However, it does not require the intensity of involvement implied by the CDC approach and so permits a single coordinator to service a far greater number of hospitals.

Strategic Planning and Hospital Selection

Which hospital to concentrate on is a critical decision for an organ procurement agency. Most agencies think far too little about this decision, and, as a result, many disperse their efforts too broadly. The desire to work in as many hospitals as possible is an understandable one; it is the desire to obtain access to as many potential donors as possible. However, some agencies claim to work in 150 hospitals and will actually obtain organs from as many as 40 in the course of several years. Yet my own work and that of the CDC indicate that only a small percentage of hospitals provide the bulk of the donors; most OPAs spread themselves too thin.

The CDC methodology involves extensive reviews of medical records in part to determine which hospitals ought to be worked with. This is certainly the most accurate approach and necessary in a research/demonstration project, but it is far too costly to be used routinely. In their excellent Georgia demonstration, one third of the staff were involved solely in record reviews. Employing cruder rules of thumb and using that third person to increase ones organ procurement capacity are probably better approaches for most OPAs.

In practice the selection of appropriate hospitals must consider local medical politics and the receptivity of critical staff within a given hospital. Beyond that certain "first cuts" can be done. In almost every OPA so far studied, suburban hospitals and regional trauma centers were the best source of kidneys. Rural hospitals are often too small and without a staff neurosurgeon or neurologist to declare brain death. Indeed they often transfer potential donors to hospitals better suited to deal with their injuries. In addition, for reasons not completely clear, many inner-city public hospitals are very poor sources of referrals.

The most productive hospitals in which to invest staff time are probably those that have provided a moderate number of referrals in the past. Units that refer one patient a year probably cannot be effectively worked with. In part this is because their patient mix may be inappropriate but it also reflects the difficulty of motivating a staff that gets the satisfaction of actually producing a donor so rarely. On the other hand, the most active hospitals do not need to have surveillance. They obtain sufficient feedback from actual donations to sustain their involvement, and the coordinator's personal relationship is maintained in the best way - by working with nurses to retrieve organs. The best return on investment therefore probably lies in hospitals between these extremes. It is desirable for an OPA to limit the number of hospitals to fit its resources rather than to spread its resources to match all those hospitals willing to be involved.

The Wastage of Kidneys

The steps recommended up to now could increase the number of kidneys procured by as much as 100%. However, the number of organs procured is not the same as the number of organs actually transplanted. In 1981 23% of all kidneys obtained from cadavers were not transplanted, they were wasted. Eighteen percent of those procured by independent agencies were wasted.) Reduction of this "wastage rate" could contribute to the nation's supply of organs in an important way. As in so many areas there is great variation among OPAs in terms of their wastage rates. Limiting ourselves to Independent Agencies, we find rates that vary from 6% to over 40%. The causes of these variations are not known and research into them would certainly repay the government in terms of additional usable organs, and as any decrease in wastage decreases the average cost of a kidney, it would probably repay the government directly as well.

The probable causes of organ wastage are four; anatomical or biological shortcoming in an excised organ, surgical errors in excision, administrative shortcomings that cause the organ not to be placed with a recipient and non-existence of a suitable recipient. Cause one and four are uncontrollable but their overall contribution to wastage is not known. In addition, it ought not be assumed that the lowest rate is the best; a very low wastage rate may reflect an excessively conservative procurement policy that fails to obtain many suitable organs. All of these questions are easily researchable and HCFA ought to direct its attention toward them.

Modifying the Voluntary System

In the last few years, as recognition of the kidney shortage has spread, there has been a number of proposals for altering our present organ procurement approach. In general, and to varying degrees, these proposals involve the introduction of incentives or coercion into the system as a way of increasing the rate of donation. In my judgement, these proposals are premature and, in some instances, reckless.

It is possible that the reforms I have discussed will provide a supply of organs sufficient to our needs in the future, in which case there is no reason to abandon a successful approach. However, it must be admitted, that it is also possible that the demand for organs, renal and non-renal, will outpace the supply that our present purely voluntary system can provide. We are apparently on the verge of important changes in the transplantation field, new organs are being transplanted and new drugs are being developed. These changes could sharply increase the demand for transplants as both the range of potential recipients increases and as higher success rates make the transplantation option relatively more attractive. We ought to prepare for this eventuality now.

What follows is a brief evaluation of the more prominent modifications of our present voluntary system. Some of these evaluations are tinged with trepidation, some with explicit skepticism. At our present state of knowledge, the best and most hopeful of them ought not to be tried; right now, we simply know too little of the effect of introducing incentives or coercion into the procurement process. In the view of many in the organ procurement business, the entire process is fragile and could be dangerously disrupted by ill-thought-out changes. I therefore urge, in the strongest terms, that a slow and scientific inquiry be made into the probable effect of any proposal before it be instituted. If such a process can be started before the pressing exigencies of an increased organ shortage are felt (if they will be felt at all), we can proceed in the future with far greater certainty and far less risk.

Plans for altering the Consent Process

Two plans have to be discussed for altering the present process of consenting to become an organ donor: one would require everyone under 65 with a driver's license to respond "yes" or "no" to the question of whether they are willing to become a donor; the other alternative is to institute an "assumed consent" law like those now existing in certain European countries[27].

I am very skeptical of both alternatives. The more modest of them, requiring a declaration, is, in my judgement, neither enforceable nor desirable. I am not sure that is is legally permissible to require drivers to make such a declaration; I am reasonably sure that it is practically impossible to enforce such a law if passed. Even if passed, it would not serve to increase the number of donations.

Under the Uniform Anatomical Gift Act, every person has the right to direct that his or her organs be donated after death. (Although, admittedly, few do.) Yet, except under extraordinary circumstances, no OPA I know of will retrieve an organ solely based on such a declaration. Even when a signed donor card is found (a legally binding document under the Gift Act), the donor's family is asked to sign a consent form. No hospital, or OPA, wishes to take the risks of entering into a conflict with a bereaved family. In part, this represents their unwillingness to increase the family's grief and, in part, their appreciation of public impact of, say, a bereft mother accusing a hospital of mutilating her daughter. No single donation is worth that risk.

Requiring people to make a declaration would not change this. A "yes" would still have to be validated by the family - although such a declaration would be a significant aid in obtaining their consent. On the other hand, a "no" would present a virtually insurmountable obstacle to obtaining family consent. This approach strikes me as exposing the organ donation process to very high risks for extremely speculative gains.

Most of the same objections can be applied to the "presumed consent" approach: is it a politically practical step and would it change hospital and OPA behavior? It certainly has a better chance of changing procurement agency behavior as it would insulate the procurement process from public attitudes. On the other hand, its overall impact on the number of organs procured is unclear. Some European nations already use such a system yet, based on rather confused data, none appear to do so well as the U.S. in organ procurement. In any case, we are fortunate in this matter as we have others doing the experimenting already. Certainly an inquiry into the European experience with "presumed consent" must precede the implementation of this alternative.

"Direct" Incentives for Donors

As an alternative to altering the consent system, several people have suggested providing direct incentives to families, or individuals, who agree to donations. These incentives take a number of forms: direct payments to families, assumption of certain medical or funeral expenses, tax credits, etc. I will not attempt to evaluate the advantages and disadvantages of each alternative but certain general considerations ought to be mentioned. Before any such system can be considered, three kinds of questions must be answered: how will it affect those already willing to donate; is it cost effective; and how will it affect the medical professionals involved in donor referral?

The most basic question to be asked of any incentive system is whether it will increase the total number of donations. To a large degree, this will depend on how it affects those groups presently willing to donate. Some involved in organ procurement fear that, in the atmosphere of grief and guilt that surrounds most donations, the suggestion that the survivors might profit in any way from the donor's death would decrease the likelihood of permission. Whether this impressionistic view is valid remains to be tested, as does the different effects of various ways of providing direct incentives to donors or their families.

A second relevant issue is cost. Presently, some 2200 donors are obtained each year without payment. If each of these were paid, say $500, the government would have to spend $1.1 million simply to be where we are now.

This would be a good investment if the total number of donations went up sharply, a poor one if the total went up only several hundred.

Lastly, it is necessary to consider how paying the donors will affect the involved medical professionals. All involved in organ donation recognize that the primary bottleneck is not family permission but donor referral. If the willingness of nurses and doctors to make referrals is decreased by the dimunition of altruistic motives on the part of donors, then such a step would be counter-productive. This, too, is a matter for inquiry.

Direct Incentives for Medical Professionals

The issue of incentives for donor families naturally raises the analogous issue of such incentives to encourage medical professionals to participate more actively in the referral process. Direct money payments to such people raises some difficult ethical and legal issues - although systems much like this are in use in some places in the U.S. However, the efficacy of alternative types of incentives (education credits, certifications, employment benefits, etc.) ought to be considered. The question here is, is it possible to design a reward package consistent with medical ethics that would increase the motivation of critical medical professionals. As a practical matter, such a package would be directed primarily at nurses.

One approach to developing such a package might entail the involvement of hospital administrations in organ procurement. As employers, the hospitals may be in a position to provide work-related incentives to nurses without raising issues of conflicts of interest. Up to now official hospital involvement in organ procurement has been minimal. Little has been asked of hospitals and little offered to them. Legal permission to operate a procurement effort within the institution was required and all that was offered was payment for the use of supplies and facilities.

So a little considered, but possibly very effective, place to initiate an incentive system into organ procurement is at the hospital level. If we find that the present voluntary approach is not sufficient, applying incentives to hospitals as organizations may act both to increase access to more hospitals and may also provide an effective methodology for motivating medical professionals with a minimum of risk. How to obtain this increased help from hospitals is, once again, a matter that bears inquiry.

Non-Renal Organs

Before I close, it is important to mention a major change beginning in the transplantation world and its implications for organ procurement. In the last several years, there has been progress in the transplantation of non-renal organs. Both liver and heart transplants are being done frequently at certain medical centers, the commencement of pancreas transplant programs is being considered at several others. It may be that, in the next few years, the transplantation of non-renal organs will represent a significant percentage of all transplants done in the United States.

Such an eventuality represents an important change in the world of organ procurement agencies. Throughout this testimony, I have referred to these agencies as "organ" procurement agencies, and so they refer to themselves. Legally speaking, however, they are "kidney" procurement agencies. With trivial expectations, each is totally funded by the End-Stage Renal Disease Program, a program that only pays for kidney acquisition. In practice, however, they have already exceeded that limitation. Almost all organ procurement agencies routinely attempt to retrieve corneas and, frequently, skin and bone as well. The added costs of such efforts are minimal as the tissue-specific banks usually do the actual excision themselves. All the agency does is ask permission of the family, make arrangements in the hospital, and contact the eye, skin or bone bank. Government ignorance or benign neglect has simply allowed these organ procurement efforts to "piggy-back" on kidney procurement without cost.

As the number of liver and heart transplants has increased in the last few years, "kidney" procurement agencies have taken responsibility for locating these organs as well. The transplant centers needing such organs have reembursed the agencies for the additional costs. So long as the total number of non-renal transplants is 2 or 3 percent of the number of kidney transplants, there is little problem with this informal, ad hoc approach. But what will occur when the percent is 10 percent, or 30 percent, or even 60 percent! Clearly, certain policy guidelines are needed.

The government has a limited number of options and a substantial number of problems to resolve. The present organ procurement system will procure non-renal organs regardless of government preferences. Indeed, no real alternatives exist. Parallel organ procurement systems, one for kidneys - funded by the End-Stage Renal Disease Program - and another procuring non-renal organs, are clearly an absurdity. What the government must decide, therefore, is who is going to pay for non-renal organs, how the cost of organ procurement is to be allocated among different organs, what are permissible charging procedures for non-renal organs, etc. In short, it must decide exactly what the relationship between renal and non-renal organ procurement will be and how that relationship will be played out within the organ procurement agencies.

The final form of that relationship will determine the final form of the nation's organ procurement agencies. For this reason, the capacity of these agencies to function effectively in this new environment ought to be a factor in the final policy decision. If these agencies are left to face a dozen reembursement systems, a dozen organ-sharing systems and several dozen different payers, they will flounder. Most organ procurement agencies do not have the managerial or financial expertise to operate such a system, nor would the impact on organ acquisition cost of such complexity be desirable.

Steps need to be taken in this matter now before the scale of the problem begins to interfere with organ procurement. At present, only the small scale of non-renal transplants is keeping that part of the organ procurement effort from chaos. Laudable attempts by some members of the North American Transplant Coordinators Organization to develop ad hoc solutions can only be considered a stop-gap measure; a permanent, effective solution can only come from Washington.

The problem is a complicated one. It may have important financial implications for the government. It will certainly play a major role in defining the shape of the nation's organ procurement system and so it will affect the availability of organs for transplantation. The final responsibility lies with HCFA and, as new law may be necessary, the Congres. The sooner work begins on the important issue, the better.

FOOTNOTES

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4. Fox, Renee and Swagey, Judith, The Courage to Fail, University of Chicago Press, Chicago, 1978.
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10. Caplan, Arthur, "Kidneys, Ethics and Politics: Policy Lessons of the ESRD Experience," Journal of Health Politics, Policy and Law. Volume 6, Number 3, Fall 1981.
11. Fox, The Courage to Fail, p. 205.
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17. Prottas, Jeffrey, "Encouraging Altruism: Public Attitudes and the Marketing of Organ Donation." Milbank Memorial Fund Quarterly: Health and Society, forthcoming.

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23. Prottas, Jeffrey, "Encouraging Altruism: Public Attitudes and the Marketing of Organ Donation."

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Mr. GORE. We are really under a time constraint now.

I am going to start your testimony, Winifred Mack. We have a close and important vote on the floor, and we are going to have to finish up the hearing by 2 o'clock. So what I am going to do is start your testimony and then interrupt it for the vote shortly, and then we will come back and have some brief questions.

So please proceed. We will put your prepared statement in the record. If you could summarize portions of it, that would be fine.

Ms. MACK. I have cut it down in my verbal testimony.

STATEMENT OF WINIFRED B. MACK, PRESIDENT, NORTH AMERICAN TRANSPLANT COORDINATORS ORGANIZATION, SUNY AT STONY BROOK

Ms. MACK. Mr. Chairman and members of the committee, as president of the North American Transplant Coordinators Organization, I welcome the privilege of testifying before this committee on behalf of the members of NATCO.

The North American Transplant Coordinators Organization is a national, nonprofit organization representing 365 professionals in the United States and several foreign countries. Our dedication is that there be a better quality of life for thousands of patients with end-stage organ failure and a respect for those who shared.

NATCO members represent various aspects of the transplant community, including physicians, nurses, and allied health professionals working with the organ recipient as well as those whose main objective is to obtain and distribute the valuable human tissue so direly needed by the waiting victims of end-stage organ failure.

To this end, our members provide information to medical personnel and the general public regarding all aspects of organ transplantation. In addition, NATCO works to disseminate information concerning new techniques in organ procurement, preservation, and transplant surgery to its members.

Kidney recovery and transplantation became a reality in 1972 when the Federal Government enacted H.R. 1, which provided, under medicare, that persons with kidney failure would receive full medical treatment. To support these activities, a new breed of professional known as the transplant coordinator evolved.

Most often, coordinators come from some other health background. Many of us are nurses or physicians' assistants; some are medical laboratory technologists; a few from related areas such as social work or psychology.

With the guidance of transplant surgeons and other physicians as well as input from the clergy, public relations and media persons, administrators, legal consultants, and other experts, the profile of the transplant coordinator was developed.

Today, although still young by comparison to other groups of health professionals, NATCO has established a training program for new coordinators as well as ongoing continuing education programs to assist in the sharing of information and techniques utilized by its members.

Additionally, several transplant institutions have opened their doors to other centers wishing to train new personnel.

The term "coordinator" aptly describes the essence of our function, and the role may vary according to institutional needs. Specific details are in my written testimony.

Some coordinators deal specifically with the transplant recipient. Other coordinators have responsibilities primarily to organ procurement, which includes development of local hospitals as donor referral sources. Each procurement center has a 24-hour hotline, and a coordinator is available day or night to assist the donor hospital with the legal issues, medical management of the donor, obtaining consent from the appropriate next of kin, and organizing the surgical team for the recovery of organs.

If the organ cannot be used by the local transplant organ, using a national computer system, the coordinator may arrange for sharing and transporting of the recovered organ to another center in a time period short enough to insure its viability.

Transplant centers have long recognized the need for public education. As individuals, or in concert with other organ recovery programs, their coordinators have developed materials such as brochures, donor cards, bumper stickers, poster campaigns, slide shows, et cetera, for presentation in schools, local community groups, civic organizations, churches, health fairs, and the like.

They keep channels of communication open with the media, being available to answer reporters' questions, perhaps speak on local and national television and radio programs, and encourage and/or assist in the development of public service announcements. Needless to say, one person cannot handle all the responsibilities described, and many programs have few persons hired under the general title of transplant coordinator.

It must be recognized, however, that these centers work under conditions of extreme austerity, and coordinators have learned to tap all available resources to insure the efficacy of their programs.

Collectively, transplant coordinators, under the aegis of NATCO, have addressed some of the problems existing on a national level.

On September 23, 1982, NATCO inaugurated a formal system to disseminate information concerning the need for extrarenal organ donors to procurement programs throughout the United States and Canada and to assist transplant coordinators and physicians in the placement of these organs for transplantation.

Mr. GORE. Ms. Mack, if you could pause there, we will recess for approximately 7 minutes and come back and finish up your testimony.

Ms. MACK. Fine.

[Short recess taken.]

Mr. GORE. The subcommittee will come back to order.

Ms. Mack, you were proceeding with your statement. Please go ahead.

Ms. MACK. Thank you, Mr. Chairman.

A recorded telephone message updated approximately twice a day provides a listing of urgently needed hearts, livers, lungs, heart/lungs, and pancreata for patients awaiting transplantation at participating centers.

The 24-ALERT system operates 24 hours a day and gives details of extrarenal donor requirements including organ needed, blood type, age, size, cross-match requirements when needed, geographical recovery area, and 24-hour referral number. There are currently 15 transplant centers listing their extrarenal organ needs with 24-Alert.

To date, 24-ALERT has facilitated the recovery and transplantation of 90 extrarenal organs, including the livers recovered for Jaime Fiske and Brandon Hall and Justine Pinheiro, cases which have received recent media attention.

NATCO 24-ALERT is a free, voluntary service easily accessible by telephone to coordinators in hospitals anywhere in the country by simply dialing 24-ALERT. I wish to stress, however, that informal referral of extrarenal organs has been in existence and common among our members since 1978.

On April 4, 1983, 800-24-DONOR was established by NATCO; 800-24-DONOR is an information and referral number for professionals, possibly to be expanded for public information in the near future. Staffed by NATCO members, it is designed to facilitate and enhance procurement programs throughout the country by referring the caller to the nearest organ recovery center in his area. Steps are currently being taken to publicize this number through professional journals and mailings to the community it will best serve.

As previously mentioned, the NATCO training and development course is the only established professional training course provided for new coordinators at this time. In addition, a desk-side reference manual is now in the final stages of preparation for use both by procurement and recipient coordinators.

Annual educational meetings serve to update, improve, and share current knowledge pertaining to organ procurement, preservation, and transplantation. Recognized leaders from various areas of transplantation, as well as representatives from governmental and private agencies, are invited to speak to our membership on topics of common interest related to procurement, preservation, general education and clinical application.

All future meetings will be held in conjunction with other important meetings of the transplant community, enabling our members to glean information from these prestigious groups.

In addition to the above major endeavors accomplished by NATCO, individual committees are working diligently on projects, short and long term, to attain specific goals and objectives of the organization.

With the general background of transplant coordinators and their representative organization, NATCO, presented herein, I feel qualified to present the following recommendations to this committee for your consideration.

Although over 30 States have thus far enacted some form of brain death legislation, for the remaining States, the physicians' and hospitals' fear of litigation looms ominous. Passage of a brain death law, and the media attention which generally accompanies it, also serves to educate the public about this difficult-to-understand phenomenon.

Imagine yourself, Mr. Gore, standing before the grieving family of an 18-year-old boy who, while on his way to a part-time job, was shot in the head by a couple of joy riders passing by. The respirator hisses every few seconds; the cardiac monitor beeps; and the boy lies motionless in his bed. The doctors have just informed his parents that he is dead, but they know there is a heartbeat, and heartbeat has always meant life to them.

Yesterday, they had a perfectly healthy, normal son. Today, they are told their son is brain dead, whatever that means. Imagine yourself trying to explain to this family that brain death is really death. And then imagine asking them to think of somebody else and to donate his organs for transplantation. They are frightened, they are confused, they are angry, and the question which comes to mind is, "Is our son really dead, or do they just want his organs?"

Brain death legislation will not answer all of the questions all of the time, but if the issue is out in the open with legal support, it somehow becomes clearer, and the consideration of organ donation by individuals before their death becomes more likely.

We suggest that, using the definition recommended by the National Conference of Commissioners on Uniform State Laws, you strongly urge the 50 States to adopt brain death legislation.

Second, although our efforts at a local level in our own donor referral hospitals have gone a long way, we in this field are painfully aware of the lack of understanding by our colleagues in the health professions as to the legal, ethical, and medical issues surrounding organ donation and transplantation.

We hope that NATCO's 800-24-DONOR number will alleviate some of the problem. However, we recognize that a more broad-based program is needed. An aggressive campaign of presentations such as seminars to groups of professionals via local and national associations and distribution of written materials would be helpful.

NATCO offers the following specific suggestions: (A) appropriation of funds, perhaps in the form of NIH grants, would assist in the development of professional educational programs and tools.

(B) Recommendations to State agencies entrusted with the responsibility of licensing of health professionals that information related to organ transplantation and donation be incorporated into curricula and questions pertaining to these issues be included in certifying examinations.

(C) A requirement that all hospitals receiving medicare reimbursement be mandated to have written policies and procedures for brain death and organ donation.

We have, during these hearings, witnessed the testimony of desperate parents anxiously awaiting the availability of a cadaver donor organ for their children. Our hearts ache for these parents, and we truly appreciate their need to do all humanly possible to achieve their goal.

However, transplant coordinators are acutely aware that there are many Jaime Fiskes and Brandon Halls in this country in need of livers and thousands of patients awaiting the availability of renal as well as extrarenal cadaver donor organs.

It is easy to relate to one innocent baby's face as it comes across the TV screen into our homes. And we as coordinators acknowledge that the plea made for one child indeed increases, albeit only temporarily, organ donation in general. But what of the mother of two young children who fears that, for lack of a transplant, she will not live long enough to see her babies reach adulthood; or the man in whom renal failure has caused sterility and who may never realize the joy of fathering a child?

It is imperative that the citizens of this Nation become aware that organ transplantation is a therapeutic modality past stages of experimentation and a viable alternative to life on a dialysis machine or blindness or, worst of all, death.

Great concern has been expressed during these hearings as to the equitability of organ distribution to the waiting recipients. Suggestions have been made in the form of a computerized matching system or a first-come, first-served basis.

National systems such as the computer available through the United Network for Organ Sharing, or NATCO's 24-ALERT, already exist to facilitate the most effective utilization of recovered donor organs. It must be appreciated, however, that in the world of medical science, a computer is only a tool to assist but not to substitute for the trained clinical judgment which must be exercised in the care of the human patient.

In varying degrees, depending on the specific organ in question, recipient selection is made on the basis of tissue matching, medical urgency, length of time a patient may be waiting on the list, geographical location, donor-versus-recipient age, size and weight, or any combination of these factors. What looks good in the computer printout is not necessarily good in clinical application.

The family that donates an organ with the expressed intention that it go to a particular recipient, or even a patient of the same race, ethnic background, or age of the donor should be told that such stipulations might result in the inability to find such a compatible recipient, or, more importantly, the inevitable rejection of that transplanted organ.

Education of the general public about specific advances in therapy have often resulted in pressure on the medical community to utilize new techniques or alter long-accepted practices. We believe that mass public education will raise the consciousness of American citizens, help them to more fully understand the complexity of these issues, and ultimately stop the senseless waste of valuable human tissues.

NATCO makes the following suggestions:

(a) A national coalition of organizations who have interest in the recovery of human organs—eyes, skin, kidneys, liver, heart, bone, et cetera—could pool their efforts and expertise to produce both public and professional educational materials on all aspects of organ donation and transplantation.

With input from the fields of medicine, advertising, media, and public relations, fundraising, law, clergy, et cetera, a national campaign could be launched to provide this informational source. Once again, money in the form of grants could be used to seed this agency.

(b) NATCO's Education Subcommittee for Public Education has worked with both the National Kidney Foundation and the American Medical Association to increase organ donation. This year, the first session of the 98th Congress introduced Senate Joint Resolution 78, to authorize and request the President to issue a proclamation declaring this week, April 24-30, 1983, as National Organ Donation Awareness Week. We ask this committee to recommend that such a week be identified annually.

Finally, the Members of Congress, each represent leadership in their local constituencies. We urge this committee to request each of its colleagues to return to their home States, ask for time from their local television stations, and publicly sign an organ donor card such as the one you have before you.

This demonstration of moral leadership by political leaders will go a long way in establishing organ donation as a natural sequel to death.

I thank you very much.

[The prepared statement of Ms. Mack follows:]

TESTIMONY OF
WINIFRED B. MACK, PRESIDENT
NORTH AMERICAN TRANSPLANT COORDINATOR'S ORGANIZATION

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE:

My name is Winifred B. Mack, R.N., B.S.N., M.P.A.(candidate), President of the North American Transplant Coordinator's Organization and a Transplant Coordinator at the State University of New York, University Hospital at Stony Brook, Long Island, New York. I welcome the privilege of testifying before this committee on behalf of the members of NATCO.

The North American Transplant Coordinator's Organization (NATCO) is a national, non-profit organization representing 365 professionals in the United States and several foreign countries. Our dedication is "that there be a better quality of life for the thousands of patients with end-stage organ failure. . . and a respect for those who shared." NATCO members represent various aspects of the transplant community, including physicians, nurses and allied health professionals working with the organ recipient, as well as those whose main objective is to obtain and distribute the valuable human tissue so direly needed by the waiting victims of end-stage organ failure. To this end, our members provide information to medical personnel and the general public regarding all aspects of organ transplantation. In addition, NATCO works to disseminate information concerning new techniques in organ procurement, preservation and transplant surgery to its members.

Kidney recovery and transplantation became a reality in 1972, when the Federal Government enacted HR-1, which provided, under Medicare, that persons with kidney failure would receive full medical treatment. To support these activities, a new breed of professional, known as the Transplant Coordinator, evolved. Most often coordinators come from some other health background - many of us are nurses or physician's assistants, some are medical laboratory technologists, a few are fom related areas such as social work or psychology. With the guidance of transplant surgeons and other physicians, as well as input from clergy, public relations and media persons, administrators, legal consultants and other experts, the profile of the Transplant Coordinator was developed. Today, although still young by comparison to other groups of health professionals, NATCO has established a training program for new coordinators, as well as on-going continuing education programs to assist in the sharing of information and techniques utilized by its members. Additionally, several transplant institutions have opened their doors to other centers wishing to train new personnel.

The role of a Transplant Coordinator may vary according to institutional needs. Some coordinators deal specifically with the transplant recipient, assisting the physicians with the determination of medical suitability, arranging for necessary laboratory and diagnostic testing, communicating with other health care providers (physicians, dialysis units, etc.) to keep current on the status of the patient, providing for the collection of frequent blood samples for tissue matching with specific donor organs, and educating and preparing the patient emotionally and otherwise for the future transplant procedure.

Other coordinator's have responsibilities primarily to organ procurement. This may include development of local hospitals as donor referral sources by meeting with administrators, medical boards, nursing and other ancillary personnel to assist in the formulation of policies and procedures for the determination of brain death and organ donation. Frequent surveillance visits and continuing-education programs are offered as a means of keeping organ donation "alive" in the minds of the professionals in these hospitals. Coordinators develop protocol manuals, posters, slide shows, telephone stickers, etc., for distribution in hospital emergency rooms, critical care units and the like. Each procurement center has a 24 hour "hot line" and a coordinator is available day or night to assist the donor hospital with the legal issues, medical management of the donor, obtaining consent from the appropriate next-of-kin, and organizing the surgical team for the recovery of the organs.

When the organs are obtained, coordinators may be present in the operating room to help in their preparation and preservation for transplantation. Within the transplant center they may arrange for the final cross-matchng and then admission of the suitable recipient. Alternatively, if the organ cannot be used by the local transplant program, using a national computer system, the coordinator may arrange for the sharing and transporting of the recovered organ to another center - all in a time period short enough to ensure its viability.

Transplant centers have long recognized the need for public education. As individuals, or in concert with other organ recovery programs, their coordinators have developed materials such as brochures, donor cards, bumper stickers, poster campaigns, slide shows, etc., for presentation in schools, local community groups, civic organizations, churches, health fairs and the like. They keep channels of communication open with the media, being abailable to answer reporters' questions, perhaps speak on local or national television/radio programs, and encourage and/or assist in the development of public service announcements.

Needless to say, one person cannot handle all the responsibilities described and many programs have a few persons hired under the general title of Transplant Coordinator. It must be recognized, however, that these centers work under conditions of extreme austerity and coordinators have learned to tap all available resources to ensure the efficacy of their programs.

Collectively, Transplant Coordinators, under the aegis of NATCO, have addressed some of the problems existing on a national level:

1. NATCO's 24-ALERT On September 23, 1982, NATCO inaugurated a formal system to disseminate information concerning the need for extrarenal organ donors to procurement programs throughout the United States and Canada, and to assist transplant coordinators and physicians in the placement of these organs for transplantation. A recorded telephone message, updated approximately twice a day, provides a listing of urgently needed hearts, livers, lungs, hearts/lungs, and pancreata for patients awaiting transplantation at participating centers. The

24-ALERT system operates 24 hours a day, and gives details of extrarenal donor requirements including organ needed, blood type, age, size, cross-match requirements when needed, geographical recovery area and 24 hour referral number. There are currently 15 transplant centers listing their extrarenal organ needs with 24 ALERT. To date 24 ALERT has facilitated the recovery and transplantation of 90 extrarenal organs (34 hearts, 55 livers, 1 heart/lung block) including the livers recovered for Jamey Fiske, Brandon Hall, and Justine Pinheiro, cases which have received recent media attention. NATCO 24 ALERT is a free, voluntary service, easily accessible by telephone to coordinators in hospitals anywhere in the country by simply dialing 412-24 ALERT. Institutions who wish to add a potential recipient to the recorded message, may do so by dialing 412-366-6777. I might add that informal referral of extrarenal organs has been in existance and common among our members since 1978.

2. NATCO's 800-24-DONOR On April 4, 1983, 800-24 DONOR was established by NATCO. 800-24 DONOR is an information and referral number for professionals, possibly to be expanded for public information in the near future. Staffed by NATCO members, it is designed to facilitate and enhance procurement programs throughout the country by referring the caller to the nearest organ recovery center in their area. Steps are currently being taken to publicize this number, through professional journals and mailings (Journal of the American Medical Association, April 15, 1983), to the community it will best serve.

3. NATCO TRAINING AND DEVELOPMENT COURSE As previously mentioned, this is the only established professional training course provided for new coordinators at this time. In addition, a desk-side reference manual is now in the final stages of preparation for use by both procurement and recipient coordinators.

4. NATCO ANNUAL MEETING Annual educational meetings serve to update, improve, and share current knowledge pertaining to organ procurement, preservation, and transplantation. Recognized leaders from various areas of transplantation, as well as representatives from governmental and private agencies are invited to speak

to our membership on topics of common interest related to procurement and preservation, general education and clinical application. Meetings are held in plenary and simultaneous sessions and workshop format, and active participation by attendees is encouraged. All future meetings will be held in conjunction with other important meetings of the transplant community (i.e., American Society of Transplant Surgeons, The International Congress of The Transplant Society), enabling our members to glean information from these prestigious groups.

5. In addition to the above major endeavors accomplished by NATCO, individual committees are working diligently on projects, short and long term, to attain specific goals and objectives by the organization.

With the general background of Transplant Coordinators and their representative organization, NATCO, presented herein, I feel qualified to present the following recommendations to this committee for your consideration:

1. BRAIN DEATH LEGISLATION Although over 30 states have thus far enacted some form of brain death legislation, for the remaining states the physicians' and hospitals' fear of litigation loom ominous. Passage of a brain death law, and the media attention which generally accompanies it, also serves to educate the public about this difficult to understand phenomenum. Imagine yourself, Mr. Gore, standing before the grieving parents of an 18-year old boy who, while on his way to a part-time job one Saturday morning, was shot in the head by a couple of "joy riders" in a passing car. The respirator hisses every few seconds sending oxygen into his otherwise unmoving lungs. The steady beep of the cardiac monitor drones on as the boy lays motionless in his bed. The doctors have just informed these parents that their son is dead, but they know there's a heartbeat, and heartbeat has always meant life. Yesterday they had a perfectly healthy, normal son - today they are told "he is brain dead," whatever that means. Imagine yourself trying to explain that brain death is really death - and then imagine asking them to think of someone else and to donate his organs for transplantation. They're frightened, they're

confused, they're angry. And the question which comes to mind is, "Is our son really dead, or do they just want his organs?"

Brain death legislation will not answer all of the questions all of the time, but if the issue is out in the open, with legal support, it somehow becomes clearer, and the consideration of organ donation by individuals before their death becomes more likely. We suggest that, using the definition recommended by the National Conferrence of Commissioners on Uniform State Laws, you strongly urge all 50 states to adopt brain death legislation.

2. PROFESSIONAL EDUCATION Although our efforts at a local level in our own donor referral hospitals have gone a long way, we in this field are painfully aware of the lack of understanding by our colleagues in the health professions as to the legal, ethical and medical issues surrounding organ donation and transplantation. We hope that NATCO's 800-24 DONOR will alleviate some of the problem. However, we recognize that a more broad-based program, geared towards professional education and information is needed. Presentation such as seminars to groups of professionals via local and national associations, and distribution of written materials would be helpful.

NATCO offers the following specific suggestions:

A. Appropriation of funds, perhaps in the form of N.I.H. grants, would assist in the development of professional educational programs and tools.

B. Recommendations to state agencies entrusted with the responsibility of the licensing of health professionals, that information related to organ transplantation and donation be incorporated into curricula and questions pertaining to these issues be included in certifying examinations.

C. A requirement that all hospitals receiving Medicare reimbursement be mandated to have written policies and procedures for brain death and organ donation.

3. PUBLIC EDUCATION We have, during these hearings, witnessed the testimony of desperate parents, anxiously awaiting the availability of a cadaver donor organ for their children. Our hearts ache for these parents, and we truly appreciate

their need to do all humanly possible to achieve their goal. However, Transplant Coordinators are acutely aware that there are many Jamey Fiskes and Brandon Halls in this country in need of livers, and thousands of patients awaiting the availability of renal as well as extrarenal cadaver donor organs. It is easy to relate to one innocent baby's face as it comes across the TV screen into our homes. And we as coordinators acknowledge that the plea made for one child, indeed increases, albeit only temporarily, organ donation in general. But what of the mother of two young children who fears that for the lack of a transplant she'll not live long enough to see her babies reach adulthood. Or the man in whom renal failure has caused sterility and who may never realize the joy of fathering a child. It is imperative that the citizens of this nation become aware that organ transplantation is a therapeutic modality, past the stage of experimentation and a viable alternative to life on a dialysis machine, or blindness, or worst of all, death.

Great concern has been expressed during these hearings as to the equitability of organ distribution to the waiting recipients. Suggestions have been made in the form of a computerized matching system, or a 'first-come, first-served' basis. National systems, such as the computer available through the United Network for Organ Sharing (UNOS) , currently accessed by approximately 140 centers, or NATCO's 24 ALERT, already exist to facilitate the most effective utilization of recovered donor organs. It must be appreciated, however, that in the world of medical science, a computer is only a tool to assist, but not to substitute for, the trained clinical judgement which must be exercized in the care of the human patient. In varying degrees, depending on the specific organ in question, recipient selection is made on the basis of tissue matching, medical urgency, length of time a patient may be waiting on the list, geographical location (re: time for transporting), donor vs. recipient age, size and weight, or any combination of these factors. What looks good in the computer print-out is not necessarily good in clinical application. The family that donates an organ with the expressed intention that it go to a particular recipient, or even a patient of the same race, ethnic background or age of the donor, should be told that such stipulations might result in the inability to find such a compatible recipient, or more importantly, the inevitable rejection of the transplanted organ.

Education of the general public about specific advances in therapy have oft resulted in pressure on the medical community to utilize new techniques or alter long-accepted practices (e.g., the use of routine mamography as a prophyllactic diagnostic test for breast cancer). We believe that mass public education will raise the consciousness of the American citizen, help him/her to more fully understand the complexity of these issues, and ultimately stop the senseless waste of valuable human tissues.

NATCO makes the following suggestions:

A. A national coalition of organizations who have interest in the recovery of human organs - eyes, skin, kidneys, liver, heart, bone, etc., could pool their efforts and expertise to produce both public and professional educational materials on all aspects of organ donation and transplantation. With input from the fields of medicine, advertising, media and public relations, fund-raising, law, clergy, etc., a national campaign could be launched to provide this informational source. Once again, money in the form of grants, could be used to seed this agency.

B. NATCO's Education subcommittee for Public Education has worked with both the National Kidney Foundation and the American Medical Association to increase organ donation. This year, the first session of the 98th Congress passed S.J. Resolution 78, to authorize and request the President to issue a proclamation declaring April 24 - 30, 1983, as National Organ Donation Awareness Week. We ask this committee to recommend that such a week be identified annually.

C. Finally, the members of Congress each represent leadership in their local constitutiencies. We urge this committee to request each of their colleagues to return to their home states, ask for time form their local television stations, and publicly sign an organ donor card, such as the one you have before you. This demonstration of moral leadership, by political leaders, will go a long way in establishing organ donation as a natural sequel to death.

Mr. **Gore**. Thank you very much. We appreciate that excellent testimony. Many of your recommendations, I am certain, will be included in the report and the recommendations of the subcommittee.

I would also like to thank my constituent, Sherry Park, pioneer in tissue typing work, for her assistance in making your testimony possible here today.

We are running very short on time, and I am sorry about that, but let me just ask a couple of brief questions.

Dr. Sell, I should point out that you are an imminent and internationally recognized immunologist, and you are in fact the scientific director of the National Institute of Allergy and Infectious Diseases. Is that correct?

Dr. **Sell**. That is correct.

Mr. **Gore**. So when you project that the dramatic advances in immunosuppression which have occurred recently are but a stage on the way to complete prevention of graft rejection in only a few years, we ought to take that prediction pretty seriously.

Do you believe that it is just a few years before graft rejection will be a thing of the past?

Dr. **Sell**. Certainly, we anticipate that the vast increase in immunological research which is going on now will enable us to identify the elements of the immune system and better control them. We anticipate that in the foreseeable future, maybe not the next few years but certainly in the next decade, we will see ways of controlling this immune response that are far superior to the ways that we have today.

For example, we already have, through the new biotechnologies, ways of making very specific antibodies to hit very specific targets in the immune system. While these have not yet been used with complete success, we do note that places like the Mass General Hospital already are exploring these methods for controlling the rejection episodes which still occur despite the immunosuppressive agents that are currently available, including cyclosporin.

Mr. **Gore**. Some of the figures we received 2 weeks ago indicate that the incidence of rejection has already dropped dramatically, and it is just a new era.

You mentioned in that regard that you expect to see an explosive increase in the demand for organs for purposes of transplantation. Do you have any way of estimating the numbers involved, and could you tell us whether or not the present system is at all capable of dealing with this?

Dr. **Sell**. I am perhaps not the best one to respond to that. I cannot give you exact figures. The comment in my testimony really had to do with the fact that if we can control the immune rejection without using nonspecific toxic immunosuppressive agents that we currently have available, we will be able to extend transplantation to deal with problems that are not necessarily life threatening. This will expand the patient populations greatly and therefore expand the need beyond even those that have been discussed so widely by other members of this panel and others who have testified at this meeting.

To estimate the total need would be difficult. We are certainly talking in terms of tens of thousands of people.

Mr. GORE. Congressman Reid?

Mr. REID. I have no questions, Mr. Chairman.

Mr. GORE. We are going to have a comprehensive report with recommendations on a national strategy, and many of the recommendations that you have made on this panel will be included in our report. The recommendations of other witnesses who have appeared during the 3 days of this series of hearings will in large part also be included.

I hope that we can look forward to the day, not long from now, when we will have a national strategy to enhance the awareness of organ donation and how important it is to sustain life.

I think there are many things that obviously can be done right away, and I hope that these hearings have helped, and I hope that our report will help further.

I would like to thank the members of our last panel for their contribution here today, and I would like to thank all of the witnesses who have appeared during the 3 days of testimony. We will look forward to continuing our work with many of you and many of those others who have appeared here in our joint efforts to try to solve these problems.

Thank you very much. The hearing is adjourned.

[Whereupon, at 2:14 p.m., the subcommittee recessed, to reconvene at the call of the Chair.]

APPENDIX

Additional Material Submitted for the Record

AMERICAN ASSOCIATION OF CRITICAL-CARE NURSES

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EXECUTIVE DIRECTOR
Edward A. Shaw, MBA, PhD

April 27, 1983

The Hon. Albert Gore, Jr.
Subcommittee on Investigation
and Oversight
Committee on Science and
Technology
U. S. House of Representatives
House Annex 1, Room 822
Washington, DC 20515

Dear Congressman Gore:

On behalf of the American Association of Critical-Care Nurses, I am pleased to submit the attached document, "Organ Procurement: The ICU Nurse's Perspective," for use in your consideration of the issues related to organ procurement. I must confess to disappointment that time did not allow us an opportunity to present our testimony during the hearings. Input from nurses who are among the most significant links in the procurement process is essential. Nevertheless, we are very pleased to be able to offer this document and would hope that, should other hearings be arranged, there might be time available for us to present.

Thank you again for the opportunity to share this information with you. I look forward to seeing the recommendations of the hearings. If there is any further way in which I or the association can help in the future, I would consider it a privilege to do so.

Sincerely,

Joanne Disch

Joanne Disch, RN, MSN, CCRN
President

JD/enf

Att.

National Office: One Civic Plaza, Newport Beach, California 92660 · (714) 644-9310

AACN AMERICAN ASSOCIATION OF CRITICAL-CARE NURSES

ORGAN PROCUREMENT

THE ICU NURSE'S PERSPECTIVE

Organ transplants have long left the experimental days. At present, they maintain a high rate of success as a major surgical intervention to increase the quality and quantity of life for those suffering from severe organ dysfunction or failure. Sophistication in surgical techniques and developments in immuno-suppressive therapy have greatly increased the success of tranplantation of human organs (Cleveland, 1975). Unfortunately, relatively few of the chronically ill awaiting transplants actually receive organs. The problem appears to lie in the identification and referral of organ donors, not in their availability.

An annual estimated 20,000 Americans die suddenly from brain tumors, injury or strokes and have the potential to become organ donors (Stuart et al, 1981). These critically ill and neurologically impaired patients usually require intensive care units (ICUs) for the first few days. The nurses in the ICU have a very unique role. The high nurse/patient ratio (i.e., one nurse for one or two patients) enhances the comprehensive care of all aspects of the patient's physical illness and resulting psychosocial problems. Critical care nurses are in a position to identify, facilitate and complete the referral process of organ procurement.

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This paper will present an overview of various aspects of the problem, the role of the ICU nurse, impeding factors in the process and recommendations for improvement.

SCOPE OF THE PROBLEM

Cadaver donor transplantation has become an accepted surgical intervention to treat organ failure. Skin, corneas, livers, hearts and kidneys can be procured from appropriate donors. However, only a small percentage of the needed organs is obtained.

For example, more than 60,000 Americans presently suffer from irreversible renal (kidney) failure and are dependent upon hemodialysis to maintain life. Hemodialysis requires the patient to be placed on a machine that does the job of his nonfunctioning kidneys for four hours a day, three times a week. It costs the patient almost $28,000 a year to maintain such therapy. In contrast, a kidney transplant costs approximately $20,000 initially and $1,000 per year to maintain (Burns, 1980). Familial donors are first approached but, due to incompatibilities, over 75% are cadaver transplants (Renal Network Coordinating Council, 1982).

Of the 20,000 possible donors mentioned earlier, only 16% of those kidneys are actually obtained (Stuart et al, 1981). The supply does not come close to meeting the demand of organ transplant recipients.

Transplant centers have been developed to help facilitate the referral process; however, the number of referrals still remains low. Legal, logistical, ethical and personal obstacles of all involved seem to stand in the way of the actual donation. The nurse in the ICU setting has to deal with many of these obstacles.

A study conducted by the Center for Disease Control showed that over 74% of potential donors died in critical care units (Renal Network Coordinating Council, 1982). Due to the critical and usually sudden nature of the disease, the patient is placed in the ICU for careful monitoring of his vital signs, respiratory management and complete neurological assessment. The registered nurse is the person primarily responsible for the patient's total physical and psychosocial care. For an 8-12 hour shift, the nurse concentrates her efforts on the care of just one or two patients. She is responsible for caring for his wounds, maintaining lines and support equipment, monitoring vital signs, assisting the physician in diagnostic procedures and supporting the family. The nurse is responsible for continuity of care of the patient and his family and is constantly looking for signs of improvement.

There are a multitude of factors involved in the organ procurement process. The following section will focus on one of the variables, the role of the ICU nurse and the specific problems relating to the referral process.

THE ICU NURSE: ROLE AND PROBLEMS

The Decision for Donation: Individual and Family

The decision for organ donation is a difficult one for both the individual and family. The nurse, an informed individual in health care, often struggles with the personal commitment to organ procurement. She is involved with a personal decision making process, as well as in professional practice in assisting the family with a difficult decision.

As the public become aware of the successes of organ donations, a positive attitude toward the issue evolves (Cleveland, 1975). 70% of the population stated that they were willing to donate organs. 80.7% of nurses surveyed stated that they would be donors, but only 28.2% actually carried donor cards (Sophie et al, 1983). Although cognitively, organ donation appears to be logical, nurses as well as others find it difficult to anticipate their own death and thus make a written commitment regarding their organs. The donor card is a legal document under the Uniform Anatomical Gift Act. The witnessed signature on the card lets others know of a desire to become an organ donor in the event of sudden death (Kidney Foundation, 1980). It is a relatively simple procedure but a deeply personal decision. There is something very unsettling in making preparations for one's own death. Freud theorized that subconsciously everyone believes in his own immortality. It is a difficult thing to accept and is left incomplete by many.

Consequently, in cases of severe illness or irreversible brain injury, the decision for organ donation is left up to the family. Family members are in crisis as they await progress reports on the patient. Reports of 'brain death' introduce a new dilemma. The usual definitions of death, which to many mean the cessation of a heartbeat and breathing, are incongruous with the concepts introduced in the definition of 'brain death.' Families visit the patient in the ICU and observe the multitude of equipment and tubes required for his care. He is comatose but shows some evidence of breathing (ventilator-assisted) and a heartbeat. It is difficult for families to realize that his brain has ceased to function. The ICU nurses become primary support people for families during this time. Nurses are frequently at the patient's bedside along with the family and become an available resource for questions, progress reports and reassurance. The environment of the ICU with its monitors, machinery, intermittent alarms and incomprehensible blips is often frightening for family members. The nurse takes time to explain and re-explain all that is being done and what the monitors mean. She reassures them that most support machinery is not as uncomfortable as it seems and is there to facilitate the care of the patient.

During the crucial first one to three days in the ICU, a rapport and relationship are established between the nurse and the family. The family begins to relax and share their feelings and their experiences about the patient. Through his family, the nurse gets to know the patient as a person. The patient no longer exists as a 'body with a disease' but as a person with a career, family and personality. Thus, over a short period of time, the nurse becomes intensely involved with and committed to both the patient and the family.

Ethical Considerations

Ethical problems are not new to an ICU. Health care education has emphasized the preservation of life and functioning whenever possible (Cohen, 1977). Dilemmas in care are faced by the ICU nurses constantly in the care of transplant donors. Once a diagnosis of brain death is confirmed, the goals for treatment of the patient change. Neurological patients are usually kept semi-dehydrated to control cerebral edema (swelling) and undergo frequent neurological exams to check for improvements or deterioration in condition. Once brain death has been declared and permission for a donor organ is obtained, the patient is rehydrated to maximize kidney function, neurological checks are discontinued and cardiovascular and respiratory functions are supported specifically for the preservation of the kidneys (or other organs). Some nurses fear making an error in the management of the patient at this time due to a lack of familiarity with the policy and protocols of organ procurement (Sophie, et al, 1983).

In addition, 21% of the nurses surveyed felt that it was emotionally draining to have to care for a 'dead' body for eight hours or more. The nurse has gotten to know the patient through the family and in her mind, he is not just a body. Up to now, the energy spent by the nurse has been for the preservation of life, looking for signs of recovery and hoping with the family for improvement. The diagnosis of brain death is often disappointing and frustrating.

The patient is also occupying a bed space that may be needed by someone healthier with a chance of survival. A basic philosophical question arises: Should an ICU be used for the purpose of maintaining cadaver transplants while other patients await an ICU bed?

Nursing staff frequently becomes involved in bed space issues and room assignments of incoming patients. Depending upon the severity of the illness and the requirements for care, nurses set priorities on the utilization of bed space and thus nursing staff.

The nurse is often caught in the middle of an interdepartmental transfer of patients. For example, an ICU may not be able to accept a patient from the emergency room due to a lack of beds. A possible bed can be opened as soon as the transplant team arrives to care for the donor organ. Meanwhile, the waiting patient is cared for in the emergency room or in another department which may not be an appropriate area for the care required. It is an added stressor for the nurses in that department.

Donor Identification Process

The nurse remains the primary person in identifying possible donors. Sophie et al (1983) surveyed 312 ICU nurses on their perceptions of their role in organ procurement, personal feelings and baseline knowledge. 63% felt that nurses were the first to recognize possible donors, but felt the ultimate decision for referrals be made by the physician (65%) and the approach to the family should also be made by the physician (79%). She also found this group very knowledgeable about the criteria for organ donation, but about 25% of them did not know the policy for referral in their hospital. They were also unaware of the attitudes of the neurologists and neurosurgeons working in the unit.

Nurses possess the knowledge and awareness to recognize possible donors, but the physician is usually the person to approach the family. The physician, however, may also be dealing with his feelings about the loss of his patient and/or be unable to make the commitment to the diagnosis of brain death (Stuart et al, 1981). This physician may have been caring for the patient for many years. A sudden death may be equally traumatic for him as for the family and the nurse. He may find it difficult to discuss the options objectively with the family even if the family has introduced or accepted the idea.

The organ procurement process is often a complicated and extensive procedure. The physician may not want to make things any more difficult for himself and the family by having to deal with the needs of the transplant team.

The care of the patient is a collaborative effort between the nurse and the physician. It becomes a problem for families when there are inconsistencies in messages given them about any facet of the patient's condition. Families look to the nurse/physician team for support and stability. Family stress and disorganization are intensified when a discussion of important issues is conflicting or nonexistent. This frequently occurs when the grief of the physician becomes an obstacle in communication in the organ procurement process.

Lack of Rewards

A minority (25%) of nurses stated that caring for such patients is rewarding (Sophie et al, 1983). A retrospective study on donors' families was done by Morton and Leonard in 1979. All families were pleased with their decision to allow the donation, an option many would not have considered had someone not suggested it. The most comfort came from the knowledge that they had either fulfilled the patient's wish or that something tangible and positive had come out of his death.

The family often receives feedback about the results of the organ transplant. The nurse caring for the patient may not receive such feedback. Her memory of the final outcome of the patient's stay in the ICU is a picture of him being taken to surgery to remove the donor organs. It is an unfinished termination of the nurse's relationship with the patient.

The roles of nurses in an ICU are as patient advocate, care giver and educator of patient and family to facilitate the adaptation to his illness. In order to do this, the nurse must deal with her own grief and loss over losing a patient. Timing of each step in the organ procurement process becomes important. The family as well as the nursing and medical staff must be allowed time to accept the situation. It is often difficult for the nurse to keep an objective perspective on all these factors in an extremely busy and stressful environment.

RECOMMENDATIONS

The overall goal is to stimulate the nurse and physician to notify the transplant team about potential donors. The enhancement of the goals of the organ procurement process must be viewed from a collaborative nurse-physician perspective. The following recommendations are made based on this concept.

(1) Prepare nurses and physicians through continual staff education. Educational series need to encompass hospital procedures and criteria for donor referral, the availability and function of the transplant team (and coordinator if one is available), responsibilities and interrelationships of other departments,

and a baseline knowledge of ethical issues involved. It will also be helpful to provide guidelines in dealing with the family's grief response.

(2) Provide avenues for nurse and physician support. This support can be in the form of positive feedback on the outcome of recipients, visits to the donor center (Sophie, 1983), a reliable support person to assist nurses and physicians in dealing with their grief and loss and perceptions regarding the changing goals of patient care. An ethics committee can also function as a support system for the health team.

(3) Increase consistency of in-hospital family support. Time is of the essence in the decision making process for all involved. Additional family counseling such as a psychiatric liaison or clergy may be helpful at this time.

(4) Ongoing public education. As public awareness on the subject increases, initiation of donations from the patient and family may increase (Van Hook, 1982).

CONCLUSIONS

The present system of organ procurement is failing to meet the needs of a large population of transplant recipients. The problems lie in the many variables involved in obtaining organs for donation, not in the availability. Most decisions occur amidst a highly stressful environment and during a critical time in the patient's and family's lives. The various factors from the perspectives of ICU nurses have been discussed.

It is obvious that the nurse plays a major role in facilitating the organ procurement process. It is imperative to recognize this role and support the nurse and physician in a collaborative effort in increasing referrals. Recommendations were stated to enhance this overall goal in facilitating the process of organ procurement.

AACN AMERICAN ASSOCIATION OF CRITICAL-CARE NURSES

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The American Association of Nephrology Nurses and Technicians

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May 5, 1983

Albert Gore, Jr., Chairman
Subcommittee on Investigations and Oversight
Committee on Science and Technology
819 House Office Building, Annex 1
Washington, D.C. 20515

Dear Mr. Gore:

The American Association of Nephrology Nurses and Technicians wishes to commend you on the hearings recently conducted by your Subcommittee on the topic of transplantation. We were impressed with the depth of knowledge you and the members of the Subcommittee demonstrated on the subject and the level of concern exhibited for patients around this country in need of organ transplants. All of the issues in this very complex area were well covered during the three days of hearings.

Nurses all around our country are intimately involved in the care of patients awaiting transplantation and those receiving transplants of all types. Nurses are also responsible for recognizing and rendering care to potential organ donors, very often acting as the initial contact with transplant coordinators from local transplant programs or organ procurement agencies. In light of this knowledge, our organization was distressed about the lack of nursing representation on the panels presenting testimony before your Subcommittee.

Our Government Relations Committee has prepared the attached statement for the record on the issues raised during the transplantation hearings. We appreciate this opportunity to add nursing input to the excellent testimony already before your Subcommittee.

If you have any questions or if we can be of any further assistance to you in pursuing this topic, please do not hesitate to contact us.

Sincerely,

Dawn T. Brennan

Dawn T. Brennan, R.N.
President

AANNT National Office
North Woodbury Road / Box 56, Pitman, New Jersey 08071
Telephone: (609) 589-2187

The American Association of Nephrology Nurses and Technicians

TESTIMONY

PRESENTED TO THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

APRIL 27, 1983

AANNT National Office
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INTRODUCTION

The American Association of Nephrology Nurses and Technicians (AANNT) is a 3500 member organization involved in the delivery of care to the nephrology patient. Our members provide services to patients from the time they develop renal insufficiency (mild kidney disease), through the time when they are at end-stage renal disease (ESRD) requiring some type of dialytic therapy and transplantation. Because of this intimate involvement with renal patients, the AANNT welcomes the opportunity to submit its testimony to the Committee on Science and Technology.

NECESSITY FOR INCREASE IN ORGAN DONATION

Of the approximately 65,000 patients currently on some form of dialytic therapy in this country, experts estimate that between 10 and 20% are appropriate candidates for kidney transplantation. Currently there are approximately 4500 transplants performed per year. One major reason for this discrepancy between the number of transplants performed and suitable recipients is the lack of available donor organs. Since this is true of renal transplantation about which there has been considerable public awareness for the past twenty-five years, it is not surprising to find the lack of donor organs a problem for the transplantation of other organs.

DATA SYSTEM

Organ procurement efforts and, in fact transplantation itself, are hindered by the lack of reliable national statistics. Unfortunately, the lack of data is particularly obvious in the field of renal transplantation, the oldest and most active aspect of organ transplantation. Renal transplantation is also the only type of transplantation (except for corneal) which is government funded by the Medicare program and yet, accurate national statistics related to the number of donor organs, where they were procured, from what population group, how they were used, and patient morbidity and mortality are nonexistent. In order to advise patients about transplanation as a mode of therapy, and to refer them to particular centers, health care professionals need accurate comparative data for each transplant facility derived from those national figures. Data regarding transplant recipients that are needed are geographic and demographic characteristics, graft survival rates, and patient morbidity and mortality rates. Without such accurate data, neither we as health care professionals nor patients seeking transplanation, nor third party payors--including the federal government--nor the public at large will be able to make well-informed decisions. The AANNT supports the Department of Health and Human Services recommendation that such data collection be federally mandated as a requisite for Medicare reimbursement. Our organization, recognizing the important role that Networks play in data collection, support their continuation.

ORGAN PROCUREMENTS

The AANNT believes that effective organ procurement activities can best be accomplished through Organ Procurement Agencies (OPA's) who would be responsible for coordinating the harvesting, preservation, and transportation of donated organs and coordinating the identification of prospective recipients. In addition, public and professional education could be planned, coordinated and executed by the OPA's. OPA's should be formed to serve all transplant centers in a reasonable georgraphic region. The size of the geographic regions covered by an OPA would depend on the population, the number of transplant centers in the area, and the number of hospitals and trauma centers to be served. The OPA should include a large enough area to allow for the best use of resources and avoid duplication of services. It should be small enough to allow for reasonable travel and frequent visitation by coordinators to all facilities that might provide organ donors. Beyond the development of local OPA's we encourage regional organ-sharing networks, perhaps modeled after the Southeastern Organ Procurement Foundation (SEOPF) and inter-regional cooperation. We believe that such an organization would provide the necessary structure for effective organ procurement activities without excessive cost.

BRAIN DEATH POLICY

The AANNT supports a recommendation that the states develop statutes defining Brain Death as a criteria for the pronouncement of death. This would facilitate the collection of organs. Some states do not recognize Brain Death as the cessation of life.

PUBLIC EDUCATION

There is a need for a public education program to dissiminate the information that there are thousands of people in need of organ donation. The goal of such a public education program should be to strive to increase the public's awareness of the need for organ donation (kidneys, livers, heart, eyes, etc.) at the time of death (their own or family members). The AANNT would encourage a public education program aimed at developing a positive attitude toward organ donation. Nationally, public consciousness could be raised by a coordinated media campaign which would reach the general public. Increased use of public service spots--TV, radio, magazines and newspapers--could increase the number of donor organs available. Costs of these coordinated media campaigns should be shared by Medicare and third-party payors. At present the reimbursement policies do not allow this flexibility. Reaching the public through the education process should be part of the business of "harvesting" donor organs. Public education costs should be uniformly recognized by third-party payors. Additionally, public education programs should be aimed at increasing awareness of the need for transplantable organs in local hospitals, service organization, the media, schools, and colleges. Transplant [illegible] and transplant coordinators would do well to instill a positive attitude toward organ donation in students in high schools and colleges. The AANNT supports the continued use of organ donor cards and consent for organ donation on drivers' licenses. This points up again the need for public education so that firstcontact personnel with a potential organ donor will be alert to the victim's wishes and make the appropriate personnel aware of this.

PROFESSIONAL EDUCATION

The AANNT encourages education aimed at developing counselling skills on organ donation and transplantation in the medical profession itself. Medical schools and nursing schools should devote energy to educating their students to work with families and relations of suitable donors. This could be a condition of government funding for these institutions and programs.

PRESUMED CONSENT

The AANNT believes that this concept as presented at the Oversight Hearings may have merit in the future; however, the potential for generating negative sentiment about organ donation in the population as a whole should be anticipated and prevented. Therefore, the AANNT supports a study of public attitude in this area prior to moving in this direction.

RESEARCH

The AANNT joins the NIH and other organizations who support the funding of increased and continued research in the field of immunology. As noted by others, more data are needed in the use of Cyclosporin-A, the refinement of tissue-typing techniques, donor specific transfusions and the area or organ preservation.

EMERGENCY DEPARTMENT RESPONSIBILITY

It is the position of the AANNT that each hospital emergency department be required (as a condition of reimbursement from Medicare/Medicaid and/or as JCHA requirement for accreditation) to document on intake whether a patient is considered to be a potential organ donor candidate and further to document appropriate followup when the patient is so designated.

NATCO

The AANNT wholeheartedly supports the suggestions by the North American Transplant Coordinators Organization, in particular, the suggestion that a national organ donation awareness week be identified annually and that local representatives publicly sign donor cards in their home districts to enhance their constituents'awareness of the need for more organ donors around the country.

CONCLUSION

The AANNT strongly support the growth and development of transplantation of organs as a viable therapy for some patients. It is hoped that the disparity between the supply and demand will be narrowed. Our representatives stand ready to answer any questions.

NAPHT
NATIONAL ASSOCIATION OF PATIENTS ON
HEMODIALYSIS AND TRANSPLANTATION, INC.

156 William St., New York, N.Y. 10038
(212) 619-2727

April 25, 1983

The Honorable Albert Gore, Jr.
Chairman
Subcommittee on Investigation and Oversight
Committee on Science and Technology
House of Representatives
Washington, D.C. 20515

Dear Congressman Gore:

On behalf of the National Association of Patients on Hemodialysis and Transplantation, I would like to thank you for your interest in organ transplantation and congratulate you for holding hearings on this important and timely topic. Our Association has a membership of over 10,000 individuals with irreversible kidney failure from all states and U.S. territories. Obviously, the topic of transplantation is of great interest and concern to our members, and I would like to offer some comments for your consideration.

Before beginning, I would like to point out that as an organization we do not endorse any one therapy over other available therapies but believe that all patients should have the full range of options available to them. Currently, of course, those with kidney failure can be treated by dialysis (in several forms) as well as by a kidney transplant. Neither therapy is perfect and both have some disadvantages. Thus, some patients, myself included, have chosen not to have a transplant at the present time. However, we all are waiting and watching for continued medical advances which will make transplantation of kidneys more successful and see it as the ultimate solution to our medical problem.

As you are aware, the number of kidney transplants per year in this country are between 4,000 and 5,000. There are a number of reasons why more transplants are not done, and I want to share some of those reasons expressed by our members:

1. As I already indicated, transplantation is not yet a perfect therapy. Some patients have simply chosen to stay with dialysis until the success rate improves further.

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2. There are insufficient cadaveric kidneys available at this time. Not all states have adopted "brain death" legislation, and inclusion of uniform donor cards on drivers' licenses is far from universal. Both of these measures are needed to increase the supply of organs along with further public and medical professional education.

3. We have been surprised to learn that some transplant institutions will not include a patient on their waiting list for an organ if that person in on a list at another unit. For someone awaiting a transplant, this is a most frustrating circumstance.

4. There are financial disincentives for patients even though Medicare pays for much of the cost of the surgery. For living-related donation, there are often substantial travel and living costs in connection with the procedure. For all transplant candidates who are not physically near a transplant center, travel costs can be prohibitive for both the patient and the family.

5. Kidney patients are usually quite sophisticated about medical procedures and want to have a transplant done at the facility which has been most successful with this procedure. Information about facility-specific success rates is very difficult for patients to obtain but is greatly desired by them.

6. Medicare coverage ends 36 months after a successful transplant, but obtaining other health insurance is extremely difficult. Medical bills (e.g. repeated checkups, daily medications), even for a person with a successful transplant, are often substantial and inability to get any insurance coverage is a major problem. This has served as a disincentive in two ways. In the first instance, some people have indicated that this inhibits choosing a transplant. An even greater problem is that those individuals who have had a successful tranplant often seek to stay on the disability rolls to insure continued Medicare coverage. They also often find that employers are hesitant to hire them because of increases in insurance premiums which may result from frequent claims against the policy.

We welcome efforts by the Science and Technology Committee to remove barriers to transplantation and to encourage organ donation. We urge you to consider the following recommendations for action:

1. Institutions currently certified by Medicare to perform transplants should be prohibited from refusing to include patients on their waiting lists who are on other lists. Further such institutions should be required to publish, on a yearly basis, their success rates with both living-related and cadaveric transplants on both a short term (one year) and long term basis (five or ten years).

2. Medicare coverage should continue indefinitely for recipients of kidney transplants. We do not believe that this would increase the cost to the ESRD program in any significant amount and would undoubtedly serve to decrease funds spent by the disability program.

3. We urge that liver transplantation no longer be classed as an experimental procedure so that Medicare and Medicaid funding be available to pay the costs of this expensive but life-giving therapy. Many of our members have experienced the frustration of facing death and/or financial ruin because of failing kidneys. The extension of Medicare coverage to those with kidney failure in 1973 has saved countless lives, and we have the deepest sympathy for those with liver failure who must have a transplant to survive.

4. We ask that the federal government use its good offices to encourage changes in state laws to establish a uniform definition of death and to make uniform organ donor cards more widely available.

5. We urge continued support for research into the causes of kidney and other organ failure as well as research to improve the technical success of transplantation with a minimization of side effects.

Again, I thank you for your interest in this topic and I would be happy to provide any further information.

Sincerely,

John Newmann

John Newmann, Ph.D., M.P.H.
President

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1/83

April 13, 1983

Honorable Albert Gore, Jr.
Chairman
U.S. House of Representatives
Subcommitee on Investigations and Oversight
of the Committee on Science and Technology
Room 822 - Annex Building 1
Washington, D.C. 20515

Dear Mr. Gore:

At the invitation of the staff of your Subcommittee on Investigations and Oversight, I am submitting the attached Statement in behalf of the Medic Alert Foundation International for inclusion in the record of the hearings on organ transplantation scheduled for April 13-14, 1983.

The purpose is this Statement is to make known to the Congress, through your Subcommittee's examination of the foregoing issue, the national resources which our Foundation currently provides, and those it is planning for the future, as a nationally recognized computer-based personal medical emergency information system. Specifically, it points out how that system can be utilized to identify donors of live human organs, advise those physicians and institutions with waiting potential transplant recipients, and help process that activity.

As indicated, this is a Statement offered by three senior Foundation officials: Douglass S. Thompson, M.D., Chairman of its Board of Directors, James T. Howell, M.D., also a member of the Board who is working with its Special Task Force on Information and Communications Technology, and George M. Wheateley, M.D., also a members of that Task Force as the Foundation's Director of Professional Relations. Any one or all of these physicians is available to provide you, or members of your staff, with any additional information that might be required.

Sincerely yours,

Alfred A. Hodder

Alfred A. Hodder
President

A Charitable, Tax-Exempt, Nonprofit Foundation

*STATEMENT - PRESENTED BY THE MEDIC ALERT FOUNDATION INTERNATIONAL OF TURLOCK, CALIFORNIA REGARDING THE POTENTIAL ROLE OF ITS PERSONAL MEDICAL EMERGENCY INFORMATION SYSTEM TO ASSIST IN THE DEVELOPMENT OF A HUMAN ORGAN TRANSPLANTATION REGISTRATION AND INFORMATION PROGRAM

This STATEMENT is presented by the Medic Alert Foundation International in the hope that it will be helpful to the Subcommittee in expanding its understanding of a critical aspect of organ transplantation - - - that of the timely and accurate identification and clearance of prospective donors, and expiditing the process of providing such organs to those waiting for transplants. This information is offered for whatever help it may be in the Subcommittee's consideration of the development of public policy, and possible legislation designed to solve some of the important socio-economic and scientific problems involved with what has become a significant life-saving medical development.

- The Medic Alert Foundation is a voluntary not-for-profit organization which - - - since it was founded in 1956 - - - has provided a personal emergency medical information system to serve those individuals who have special medical conditions, or other health factors, which must be immediately made known to physicians and other medical professionals called upon to treat them in the event of a medical emergency.

- Within that system, that basic information is carried on a specially designed and internationally recognized Medic Alert bracelet or necklace, and is amplified on a wallet card carried by all subscriber-members. All of that data, and more, is also stored in the the computers based at the Foundation's headquarters in Turlock California, where it is available on a 24-hour-a-day basis to physicians and authorized emergency medical personnel, institutions and services anywhere in the continental United States, or any other part of the world.

- Currently, there are more than 2 million subscriber-members who avail themselves of these Medic Alert services, including employees of many companies who offer this coverage as a health and medical benefit.

- In its 27 years of operation, the Medic Alert Foundation and the system it operates has become a recognized world-wide organization; the internationally accepted standard for providing this very special type of protection to its subscriber-members; and acknowledged by the medical profession for providing accurate and timely service.

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*Submitted to U.S. House of Representatives Subcommittee on Investigations and Oversight of the Committee on Science and Technology in connection with its hearings on organ transplantation, April 13-14, 1983.

- As such, the Medic Alert Foundation is in a position to help address one of the principle problems in implementing live human organ transplantation programs - - - the timely and accurate identification and clearance of prospective donors - - - today and in the future. Ultimately, it might even manage and expidite the process of matching such organs to those waiting for transplants.

- Not only could the current Medic Alert symbol and system help meet an immediate need to register and identify more organ donors, but plans now under development by the Special Task Force on Information and Communications Technology of the Foundation's Long Range Planning Committee, are ideally suited to include what would be needed by such an organ transplantation registration and identification program of the future.

- The process of the timely and accurate identification and clearance of prospective organ donors is relatively uncomplicated in the case of immediately available volunteers. However, it becomes exceptionally complicated when it involves those individuals who have expressed their wish to be organ donors, but, by virtue of unpredicitible circumstances, may be expiring in an emergency unit as the result of a tragic accident.

- In addition, for the medical profession to be able to identify such individuals as organ donors; make known the availability of such organs to those who need to know; salvage those viable organs by precise surgical techniques; gain such permission as may be needed to perform those necessary procedures to extract and transfer human living tissue; and insure proper care and the immediate delivery of those organs to the proper destination, require complicated, demanding and exacting procedures.

- Many Medic Alert subscriber-members and others have already registered themselves in a variety of ways to indicate their wish to be organ donors. They can be identified, as such, on their Medic Alert bracelets and wallet cards, and by other identification including their drivers' liscenses from some states. What is needed immediately and in the future, however, is an established symbol, standard, system and network within which such potential donors can be registered, and immediately identified as organ donors.

- We submit that a recognized and standardized system would offer the protocol by which physicians, and other emergency medical personnel treating accident cases in emergency units, can be alerted that organ donations are intended, and may be performed. Within the context of that same system, they would also be able to utilize its network to advise those who are waiting for the availabiliaty of such organs to be prepared to receive them for implantation.

- As planned, the Medic Alert service of the future will not only continue to employ its internationally recognized symbol and bracelet, but will become a fully electronic computer-based personal emergency medical information system. As such, it will utilize all of the new technologies of microprocessing to encode, store, update and trasmit health and medical data suitable to such a system. In that way, it will afford all Medic Alert subscriber-members the opportunity to have the basic elements of their own medical record abstract immediately available - - - including their wish to be an organ donor - - - by carrying that information on their own person.

- In plans already under development, this would be achieved by having such information contained in a silicon chip embedded in the bracelet, or on a magnetic strip included on the wallet card. Either could be read at the scene of an accident or in a hospital or other emergency facility, by utilizing simple electronic readers. Additional information could also be called up from the Foundation-based computers on electronic terminals.

- In essence, the Medic Alert Foundation and system, as they exist today, can provide direct and immediate assistance in registering and identifying an ever-increasing number of organ donors. Plans for the future, on the other hand, have the potential for including a fully computerized registration and information system for a human organ transplantation program. Therefore, it would seem appropriate that the latter program be developed by the Medic Alert Foundation in conjunction with a cooperative effort among those agencies and organizations directly concnerned with the problems of transplantation.

STATEMENT - 4 -

We appreciate the opportunity to submit the foregoing information and ideas to this Subcommittee. We trust that what we have presented will be helpful in the work of developing the most effective and productive organ transplantation program possible.

In that regard, we would note that the Medic Alert Foundation stands ready to cooperate in any way it can toward the achievement of such a goal. Therefore, we would welcome the opportunity to explain and further detail our current personal emergency medical information system, and what is being planned for that system in the future. As indicated, that latter work is already underway, and documentation of it is available.

MEDIC ALERT FOUNDATION INTERNATIONAL

Douglass S. Thompson, M.D
Chairman, Board of Directors

Clinical Professor of Obstretics and Gynecology
University of Pittsburgh Medical School
Pittsburgh, Pennsylvania

James T. Howell, M.D.
Member, Board of Directors and
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Sugffolk County Department of Social Services
Hauppauge, Long Island, N.Y.

April 13, 1983

ESRD
NETWORK 23

End Stage Renal Disease Network of the Greater Capital Area, Inc.
4701 Willard Avenue Suite 610 Chevy Chase, Maryland 20815
(301) 652-0067

April 11, 1983

Honorable Albert Gore, Jr., Chairman
Subcommittee on Investigations and Oversight
Committee on Science and Technology
U.S. House of Representatives
House Annex #1, Room 822
Washington, D.C.

Dear Chairman Gore:

I am prompted to write this letter to you because I have come to learn of your Subcommittee's planned hearings this month on the subject of human organ transplants. Please make this communication a part of the official record of the hearing.

I personally am a renal transplant patient of five years and prior to that was a home hemodialysis patient for five years. I write this letter as Chairperson of the Patient Action Committee of The End Stage Renal Disease Network #23. This Committee includes patients in all modalities of kidney care (hemodialysis-both in center and home, continuous ambulatory peritoneal dialysis, and transplantation). Network #23 represents the National Capital Area-- the District of Columbia, Northern Virginia, and surrounding Maryland counties.

We wish to make the point that Medicare needs to be changed somewhat. The cut-off of Medicare benefits at 36 months after transplantation needs to be extended for the life of the kidney, and Medicare should cover some of the medications that transplanted kidney patients must take, at least those immunö-suppressive drugs that are common to all transplanted patients.

I am taking the liberty of sending with this letter a copy of a paper which my Committee authored on this subject in 1981 and which I entered as evidence when I testified before the Senate Finance Committee that same year in a hearing similar to those you will be holding. While the numbers in this paper are obviously a little stale, the message and principles involved are still cogent.

We are prompted to raise this issue again for a couple of reasons. The current 36-month cut-off of Medicare coverage for transplanted kidney patients is arbitrary. It must be remembered that a kidney transplant is not a total cure (like an appendectomy), but it is just another modality for treating the diseased condition and the maintenance costs continue.

Lastly, we understand that new immuno-suppressive drugs will soon be on the market and available (e.g. cyclosporin A) that are reputed to be able to elevate significantly the degree of success in organ transplantation. This, of course, would apply not only to kidneys, but to all other human organs that can be transplanted (liver, heart, etc.). Reports we have heard indicate that the success rate can be increased through the use of cyclosporin A from the current 50 percent to 85 percent. Further, some unwanted side effects will be drastically reduced, we are told.

However, cyclosporin A, while being ascribed these wonderful attributes, is also reported to be very expensive; we have heard reports that it could amount to $5,000 per year per patient. If all this is true, the mere availability of the newest drug (which patients would want, if they could have it) could present still a further financial disincentive to transplantation.

In summary, it seems to us as though the Medicare changes we recommended in 1981 (i.e., removing the current 36-month barrier and allowing routine medications be covered) still need to be considered by the Congress.

Sincerely yours,

Ernest T. Bauer

Ernest T. Bauer
Chairperson
Patient Action Committee
ESRD Network #23

Enclosure

REMOVING THE CURRENT 36-MONTH BARRIER TO CONTINUATION OF MEDICARE INSURANCE COVERAGE AFTER A KIDNEY TRANSPLANT

Background

Medicare, through Social Security Act Amendments, now covers 80% of the medical costs for End Stage Renal Disease patients up until 36 months after kidney transplant. This provision in the law covers 80% of the costs for hemodialysis, continuous ambulatory peritoneal dialysis and surgery for kidney transplantation, as well as the routine medical maintenance and hospital visits that are required subsequent to kidney transplant. This cut-off of Medicare benefits at the 36-month point is contained in P.L. 95-292 dated June 19, 1978. The specific reference is in Section 226 A,b,2 and reads as follows:

> Entitlement "shall end, in the case of an individual who receives a kidney transplant with the thirty-sixth month after the month in which such individual received such transplant, or in the case of an individual who has not received a kidney transplant and no longer requires a regular course of dialysis, with the twelth month after the month in which such course of dialysis is terminated."

Recommendation

The Patient Advisory Committee of End Stage Renal Disease Network #23 (which includes the District of Columbia, Northern Virginia, and the Southern Maryland) submits that this provision in the law which ends Medicare coverage at the 36-month point is inequitable and constitutes potentially a financial disincentive for many people to receive a kidney transplant. We recommend that Medicare coverage be extended from the current 36-month statutory limit to the life of the kidney.

Rationale

With Medicare and the Social Security Program already having invested vast amounts in many renal patients by way of years on dialysis and perhaps the cost of a kidney transplantation (or several), it makes little sense for Medicare to cease payments after 36 months because this tends only to denigrate the large investment which Medicare already has in these patients. Also, many patients with a transplanted kidney might not be able to bear the burden of the financial cost of medical maintenance on their own and would thus be inclined to take poorer care of themselves. Considering the large investment already made by Medicare in patients with a transplanted kidney, proper and adequate medical care should be almost as much a concern of Medicare as it is of the individual patient himself.

The philosophy of the federal Medicare program is to promote better and cheaper modalities for treating end stage renal disease. In the typical case (and assuming these options are medically possible), a patient is encouraged to dialyze at home (as opposed to in center dialysis) and ultimately to receive a kidney transplant. The Patient Advisory Committee of ESRD Network #23 suggests that this 36-month barrier articulated in P.L. 95-292 tends also to militate against this basic philosophy of Medicare.

We do not dismiss the important fact that expenses involved in all forms of treatment for kidney disease and its multiple related complications are prohibitive. At present, Medicare coverage is provided for 80% of the cost of dialysis and its related maintenance. Some patients have been treated by some form of dialysis since it became available. Improvements in technology and better knowledge of kidney disease promise these patients an ever-increasing lifespan. For many, it is the best, or only acceptable, form of treatment. We do not challenge their right of choice in mode of treatment.

There is a need, however, to establish an equity among all modes of treatment. The person with a kidney transplant is covered in the same manner as the dialysis patient for 36 months following a successful kidney transplant. At that time his coverage is terminated, but his expenses are not. We propose the extension of Medicare coverage to include the life of the kidney.

The initial first year expenses for a kidney transplant exceed those of the maintenance costs for the same time period with a form of dialysis. Following the first year of transplantation, however, these costs drop dramatically. But, they remain beyond the financial reach of many individuals. There are frequent lab services, expensive medication, and the preventive care so important to the transplant recipient who has his immune system suppressed. The body seeks to protect itself from the invasion of foreign matter, i.e. the kidney.

Protecting the kidney from rejection in this manner requires drug therapy. In turn, the body is vulnerable to other infections and diseases, requiring the patient to practice careful preventive medicine. Lab tests keep a check on the status of the kidney and anticipate potential problems. And there are complications. Among others, these include cataracts, lowered resistance, and bone demineralization that may require hip replacement.

In spite of these problems, a kidney transplant represents the best hope of reintegrating the person with end stage renal disease back into a more normal life. Physicians have said that while a machine may be able to maintain life, it can never equal the benefits obtained from a working organ. Loss of the kidney necessitates a return to a form of chronic treatment on dialysis.

The present termination of medical coverage for a kidney transplant after 36 months is a disincentive to the patient considering transplantation. Employers are reluctant to provide insurance coverage to a renal patient. Those patients who have entered the end stage renal disease program through disability are reluctant to reenter the job market and risk the loss of their entitlement to Medicare. While not able to handle full recovery status or return to their original type of employment, some transplant recipients could handle some form of partial recovery. They cannot, however, afford to lose their Medicare coverage. The government has a substantial investment in the person with kidney disease. It needs to encourage transplantation as an attractive alternative, whenever medically and emotionally feasible. The government needs to provide the security of continued Medicare coverage so that the transplant recipient has the confidence to attempt to return to some manner of self-reliance without fear of loss of vitally needed medical coverage.

Kidney Transplant Statistics

Since 1973, when Medicare first began to cover the costs of end stage renal disease, kidney transplants have been on the rise. The following table, which has been prepared from statistics secured from the U.S. Department of Health and Human Services presents the latest information that is available on kidney transplants for the Nation as a whole:

CALENDAR YEAR	TOTAL TRANSPLANTS	LIVING RELATED	CADAVERIC
1973	1,500	Unknown	Unknown
1974	3,179	Unknown	Unknown
1975	3,730	Unknown	Unknown
1976	3,175	911	2,264
1977	3,973	1,495	2,478
1978	3,949	1,172	2,777
1979	4,271	1,205	3,066
1980	4,630	1,270	3,360

While these statistics are impressive and show that surgical kidney transplants have risen dramatically in eight years (and in this time over 28,000 ESRD patients have been taken off the highly expensive dialysis regimen at least for a time), they do not indicate the number of persons living today in the United States with a successfully transplanted kidney. Those particular data for the nation as a whole are not available. Because of this gap in the current data colection system, we have tried instead to present as best we can the picture on the successful living kidney transplant population as we know it exists in Network #23 and then extrapolate that figure to approximate the nationwide statistic.

To present a comparable table on transplant activities for the metropolitan Washington, D. C. area and environs, the table below depicts comparable kidney transplant activity between the years 1977 and 1980 (the only years for which information is available) for ESRD Network #23:

CALENDAR YEAR	TOTAL TRANSPLANTS	LIVING RELATED	CADAVERIC
1977	95	45	50
1978	62	21	41
1979	79	28	51
1980	93	26	67

In these four years, there were 329 kidney transplants performed and, as of December 31, 1980, there were 149 of these patients who have a successful, still-living transplanted kidney. Of this 149 total, 51 (34%) have had their transplants more than 36 months and are, therefore, patients who would benefit by the legislative change we are recommending.

In an attempt to extrapolate the experience in Network #23 and apply that to the nation as a whole, we find that approximately 25% of all transplanted patients and their kidneys survive beyond the 36 month period. Utilizing the total number of transplants as listed in the first table above, there were performed since 1973 in this country a total of 28,407 kidney transplants. Assuming that 25% of those kidneys will still be functioning 36 months after the transplant (i.e. the Washington experience) , that would leave a total for the nation as a whole of 9,658 kidney transplants still functioning. Thus, there are, as best we can guess, about 9,700 patients living in this country with transplanted kidneys beyond the 36 month period, where Medicare would be picking up 80% of their expenses for routine medical maintenance and hospital visits.

Estimated Costs

The average kidney patient must report back to his renal transplant center (hospital) for extensive blood tests, urinalyses, and other medical checks, including a doctor's examination on the average of once a month. For patients who have no other medical complication, the cost of these monthly maintenance visits approximates $300-$600. On that basis, and merely extending the figures, the total cost for removing this 36 month barrier after transplant for current kidney patients would run somewhere in the magnitude of $28-$56 million per year (i.e. $300 X 12 [months X 9700 [patients X 80%). This amount can be compared to the cost of these patients remaining on hemodialysis for a year. The amount would be approximately $192,758,400.00 ($138 X 12 [treatments per month X 12 [months X 9,708 [patients . Thus, by these patients being and remaining transplanted, an estimated $136,758,400.00 to $164,758,400.00 per year would theoretically be saved.

As a secondary issue, the patient population would also advocate having the cost of monthly medications also covered by the Medicare insurance program. These routine medications for most kidney transplant patients run in the magnitude of $100-$200 for routine anti-rejection medications (such as imuran and prednizone). These costs are not now covered. Extending the same then arithmetic (i.e. $100 X 12 X 9700 X 80%), medications could cost an additional $9.0 to $19.0 million per year.

Patients on dialysis, however, have some of their medications covered by Medicare - albumin, inferon, decaducolium, antibiotics given intravenously or intermuscularly, and most emergency drugs.

For some transplant patients, their secondary insurance coverage will reimburse them for these medication costs, but not all renal transplant patients have a secondary carrier because they can't afford one or are not employed in a situation where such medical insurance is part of the normal benefits package.

In summary, the end stage renal disease patient population recommends that the current barrier which calls for Medicare insurance coverage to cease after 36 month after transplant be eliminated. Medical costs continue at a modest level for many of these patients beyond the 36 month period and our recommendation is that the insurance coverage be extended for the life of the kidney. The second point we would make is that Medicare coverage be extended to cover also the cost of routine medications which must be taken by patients with transplanted kidneys and which costs are currently excluded from excluded from payment by Medicare. Such changes, it seems to us, can be made by deleting and adding the appropriate language to Public Law 95-292. These legislative recommendations, while offered by ESRD Network #23, are also supported by other ESRD Networks around the country, as well as by the National Association of Patients on Hemodialysis and Transplantation and the American Society of Transplant Surgeons.

It must be stressed that we view these proposals as being not so much a further extension of a program, which we are fully aware is costing much more than the Congress and the Administration ever dreamed it would cost in the first instance, but rather an attempt to make more equitable the treatment of patients. Thus, our argument is one of equity; the extra costs involved are relatively minor compared to the total cost of the program and to what the costs would be if they remained on dialysis.

22 April 1983

Honorable Albert Gore, Jr., Chairman
Subcommittee on Investigations and Oversight
Committee on Science and Technology
U. S. House of Representatives
House Annex # 1, Room 822
Washington, D. C. 20515

Dear Chairman Gore:

Congratulations on your decision to tackle the gargantuan issues pertaining to organ transplantation. I would like to submit for your consideration the following observations and attached copies of reports which I feel are pertinent to the subject of organ transplantation. Please place this letter and the enclosures in the official record.

I feel well qualified to comment on some of the issues faced by your committee. My disposition and educational background are those of an activist. Much of my energy is focused on the concerns of the renal patient. And of most importance - I have a personal commitment. I received a kidney transplant in early March 1977. Prior to that, I spent two years as a hemo and peritoneal dialysis patient. My own kidneys began to fail in January of 1971 following a complicated still-birth pregnancy. In those early years, I became well-versed on what was then an infant technology. I watched anxiously as it developed, knowing its paramount importance to me. How far we have come! It is recognized now that the transplantation of kidneys is a viable alternative and we have progressed to a second phase that has turned its attention to finding the best means of improving the quality of life for a person with renal disease.

I am a member of ESRD NETWORK 23 Patient Action Committee (representing The Washington Metropolitan Area of The District of Columbia, Northern Virginia, and suburban Maryland), specializing in legislative issues. Our committee has written a paper (see attached copy) advocating the extension of medicare coverage following a kidney transplant to the 'life of the kidney'. The paper also endorses the expansion of medicare coverage to include medications which are used to treat the transplant patient.

At the present time, medicare coverage for the renal patient is inequitable. A kidney transplant is only one of several modalities for the treatment of renal disease and should not be regarded as a cure. Successful treatment requires a life-time commitment to special medication and health care maintenance. A kidney transplant is not without complications. Most of these are attributed to the current types of medication required. There is hope that the new drugs that are emerging, while very expensive, will eliminate or at least dramatically decrease these drug related complications. The technology of dialysis has also improved, making this modality also possible for long-term treatment. The equipment, supplies, and complications associated with dialysis are fully covered for the 'life of the modality'. The termination of medicare coverage 36 months after a kidney transplant is discriminatory.

In 1982 I was a member of The National Rehabilitation Task Force to End Stage Renal Disease Programs, serving on the subcommittee studying financial incentives (see attached copy of final report). The Task Force explored several areas affecting rehabilitation of the renal patient, touching on all modalities including that of kidney transplants. The points raised by The Task Force are applicable to all organ transplant programs and relevant to your current investigation.

The cost to maintain a successful kidney transplant is beyond the financial ability of the average person. It is difficult to maintain medical insurance and next to impossible to regain such insurance upon return to the work force. Lack of medical insurance may force the kidney transplant to forgo needed treatment and jeopardize the continued success of the transplant. Loss of the transplanted kidney results in a return to dialysis. Or, the prospect of inability to meet the financial requirements of a kidney transplant could be a negative factor in the consideration of which modality to choose. This decision should be based purely on medical considerations.

Regulations governing disability eligibility have no provision for a partial disability classification. Faced with the loss of medical coverage, prohibitive medical costs, and unable to make a full time return to the work force discourages any attempt to relinquish a disability classification. Changes need to be made to provide for the person who is able to return to a partial income earning status and at the same time insure the security of continued medical coverage.

In conjunction with the discussion found in the attached reports, I urge the committee to address:

(1) The extension of medicare coverage following a kidney transplant to the 'life of the kidney'. The expansion of medicare coverage to those medications necessary for maintenance of a successful organ transplant.

(2) Changes in the present disability regulations to allow for varying degrees of disability.

The findings of The Task Force and the position paper produced by ESRD NETWORK 23 PAC complement each other. Both express concern for developing the best means of reintegrating the person with renal disease into a lifestyle that is personally productive while recognizing the realities associated with a catastrophic illness. The transplanting of kidneys was a pioneer in the field of organ transplantation. Other developing organ transplantation programs can benefit from a study of the growing pains experienced in the field of kidney transplantation.

Thank you for allowing me access to this forum. I hope that my comments will prove useful to your investigation.

Sincerely yours,

Barbara M. Lindsay

BARBARA M. LINDSAY

Two Enclosures

ARMITAGE & FARNUM
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April 12, 1983

The Hon. Albert Gore, Jr.
Chairman, Sub-Committee on
Investigations & Oversight
Committee on Science & Technology
United States House of Representatives
Room 822, House Annex #1
Washington, D.C. 20515

Re: Sub-Committee Hearings on Organ Procurement

Dear Congressman Gore:

I am writing on behalf of the Midwest Organ Bank, Inc., (hereinafter referred to as MOB), a non-profit organ procurement agency and histo-compatibility laboratory located in Kansas City, Missouri. Because of the MOB's long-standing interest and concerns pertaining to the federal government's role in the End-Stage Renal Disease Program, both from a fiscal and a program standpoint, the MOB desires to make its views known to the Sub-committee in light of the forthcoming hearings on organ procurement. Therefore, we respectfully request that this letter and the enclosed documents be attached to and made a part of the record of those hearings scheduled for April 13, 14, and 27th, 1983.

The focal point of the MOB's concerns in the past and at the present is the impact of the current regulations affecting reimbursement to OPA's and histo-labs as a result of Public Law 95-292 passed by Congress in 1978. Because of those concerns, we prepared a Position Paper in the summer of 1980 which was submitted to the Sub-committee on Health of the House of Ways and Means Committee, and the Sub-committee on Health of the Senate Finance Committee. In 1980 and 1981, we spent considerable time talking with various congressmen and senators in the Missouri and Kansas region about these concerns and whether or not the reimbursement regulations could have a stagnating effect on transplantation in this country. You will find enclosed a copy of that Position Paper which outlines in some detail those areas which we felt needed to be reviewed in light of the regulatory scheme promulgated by the Health Care Financing Administration. You will also find enclosed a memorandum which is basically a summary of the Position Paper and is useful as a guide for analyzing any of those areas. We believe both documents are self-explanatory and speak for themselves, and we are hopeful that they will assist you in some way as you look into the total organ procurement program as it currently exists.

Also in relation to the fiscal aspect of reimbursement to OPA's and histo-labs, we are greatly concerned as to the impact of the new prospective reimbursement provisions of the Medicare Reform Act recently passed by Congress. More specifically, we understand that HCFA is currently studying proposed regulations to determine whether or not those funds reimbursed for tissue-typing and kidney acquisition shall be included in the kidney transplant DRG. We would like to go on record opposing the inclusion of such costs within the DRG since the rates for kidney acquisition and for tissue-typing vary distinctly from OPA to OPA and histo-lab to histo-lab. It is our position that those costs should be directly reimbursed outside the DRG formula. Otherwise, to include those costs within the allotted DRG amount would undoubtedly put the brakes on the future of transplantation as a viable medical therapy. My review and interpretation of the new statute indicates that Congress did not intend to mandate that organ retrieval and tissue-typing costs be included within the DRG formula.

We would also like to briefly address those issues which will be raised at the hearings on April 13 and 14 pertaining to problems within the organ procurement system, and specifically those areas of inquiry reflecting possible changes in the structure of the retrieval program. As to the area of inquiry pertaining to the Uniform Anatomical Gift Act, it is our opinion that the Act is certainly not the panacea for increased organ donation. Obviously the Act is helpful in reflecting the wishes of the potential donor, but the key to transforming a potential donor to an actual donor occurs within the hospital setting. Therefore, we are not certain that the Uniform Anatomical Gift Act should be the subject of any great degree of emphasis in the overall organ retrieval effort. It is the MOB's position that a greater amount of retrieval activity is directly proportional to the system or systems employed by each retrieval agency. There are many resources currently available to OPAs to increase their efforts toward this goal. The MOB, for instance, is particularly pleased with its own system for harvesting organs in the Missouri and Kansas regions as results will indicate. Perhaps reviewing successful retrieval efforts within various OPAs would be the best beginning in determining or suggesting an overall program.

Additionally, it has long been the position of the MOB that there are many areas of the country which are extremely underdeveloped in organ retrieval. It would seem logical that the first step would be to recognize and designate those areas or states of the country which are in need of an organ retrieval effort, and then possibly assist established OPAs to enter these areas and set up an organized system. However, successful OPAs have great difficulty in going about this project without some type of seed money or grant program, and where the current regulations simply do not allow for such expansion. It is this first step in bringing in the entire country within organized retrieval efforts which should be analyzed and addressed.

The second area of inquiry concerning whether or not emergency rooms should be required to document whether patients are potential organ donors is one of great sensitivity and should be approached very carefully. It is the MOB's position that utilizing statutes or regulations to screen potential donors may be too intrusive, and therefore should be approached cautiously and with input from all groups associated with retrieval activity. Again, there are many resources currently available which, if utilized by and coordinated between hospitals and OPAs could easily provide a greater degree of successful retrieval other than this proposition.

As to the third area of inquiry as to whether hospitals should be required to have on-site transplant coordinators, it is our position that again there are systems being utilized which could probably be more successful than that which may be mandated by statute or regulation. For instance, the MOB utilizes retrieval teams within a great number of hospitals within its region from which kidneys are procured. Each of these retrieval teams consist of volunteers including an ICU nurse, an emergency room nurse, a neurosurgeon, and a representative of pastoral care. The MOB has worked with these various hospitals over the past years in establishing these retrieval teams. This has allowed a tremendous amount of coordination between the MOB and the retrieval hospital in providing all aspects of donor activity from treatment to donor family ministry. The key elements of this effort are the volunteers which make up these retrieval teams. It is our opinion that this system has worked quite successfully and is the greatest substitution for any type of federal regulatory system that might be imposed.

The fourth area of inquiry concerning the utilization of tax incentives for cadaveric organ donation is of such great sensitivity that, again, it should be approached with great caution with input from all groups associated with organ retrieval efforts. The MOB does not take an official position on this issue but warns the Subcommittee that even a public forum on this issue could sensitize some individuals against organ donation. It must be remembered that organ retrieval is still somewhat in its infancy, and the evolution of social attitudes toward organ donation require a high degree of sensitivity and emotion. Thus, creating monetary incentives for organ donation may or may not be an appropriate vehicle to that end.

Regarding the fifth area of inquiry as to whether or not more regional networks should be established for the exchange, collection, and distribution of organs, the MOB would agree in general to such a proposition. The only caveat in establishing a framework for multi-regional efforts would be the role of the federal government in this area. The MOB does not feel that it would be the role of the government to take an active part in creating and managing regional sharing networks. It is the MOB's position that organ retrieval can be best managed in the private sector. However, and reflecting on our comments concerning the first area of inquiry above, federal grant projects or seed money concepts allowing established OPAs to more fully regionalize into under-developed areas of the country may be an effective role for the government. Additionally, because of its resources, the government could coordinate an exchange of ideas from the various OPAs, and thereby assisting the private sector in establishing effective regional networks for the purposes outlined in the proposition.

Finally, as to the sixth area of inquiry as to whether there should be more effective national registries of patients awaiting transplantation, the MOB fully supports this proposition, and in the same vein as its recommendations pertaining to the establishment of more regional networks. Furthermore, the current regulations stifle the opportunity of established OPAs to retrieve organs other than kidneys. Allowing organ retrieval to extend into extra-organ retrieval, and utilizing the current kidney registries now utilized, would do much to further advance activity in all phases of transplant therapy.

We hope that these comments will be of some value to your Subcommittee in its review of the total organ procurement program. If we can assist you further by answering any questions or providing further information, please do not hesitate to contact me, or the Midwest Organ Bank through its Executive Director, Mr. Larry Kist, 4006 Central, Kansas City, Missouri 64111. Thank you in advance for your attention to this information and we look forward to the findings of the Sub-committee in its efforts.

I am,

Respectfully yours,

Richard Armitage

RICHARD E. ARMITAGE
Attorney at Law

REA/jmp

Enclosures

cc: Mr. Larry Kist

MEMORANDUM

TO: Congress DATE: August, 1980

FROM: Midwest Organ Bank, Inc.

RE: Public Law 95-292

The purpose of this memorandum is to provide a general overview of the concerns on behalf of independent organ procurement agencies and histocompatibility laboratories with Public Law 95-292 and the supporting regulations. Public Law 95-292, signed into law on June 13th, 1978, amends the End-Stage Renal Disease coverage under the Medicare program. The portion of that legislation attributable to this discussion is attached to the memorandum. A more detailed discussion of the issues is located in the Position Paper prepared by the Midwest Organ Bank and presented to the Subcommittee on Health of the House Ways and Means Committee.

I. LEGISLATION

Public Law 95-292 essentially provides for reimbursement of costs through transplant centers to organ procurement agencies and histocompatibility laboratories. Following passage of this amendment, the Health Care Financing Administration promulgated certain regulations substantially placing organ procurement agencies and histocompatibility laboratories within the existing provider regulatory scheme. Prior to passage of the amendment, reimbursement was based on a negotiation of budgets between the local intermediary and the O.P.A. and laboratory within its region. Following passage of the amendment, the regulations provided for the appointment of a national intermediary with cost reimbursement to be based on cost-reports and audits conducted by that intermediary.

II. ISSUES

The specific concern of the Midwest Organ Bank with the proposed cost reimbursement policy is that it may reduce the potential for increased kidney transplants performed. The chief concerns of the Midwest Organ Bank lie in the fact that the proposed cost reimbursement policy,

1. would appear to limit the agencies' ability to fund or make capital equipment expenditures;
2. may severely hamper efforts to educate the general public in organ donation by decreasing or disallowing funds available for this effort;
3. limit the ability of the effected agencies to carry out professional educational programs in organ retrieval by decreasing or disallowing funding for these efforts;
4. may limit the agencies' ability to expand operations as needed;
5. may severely restrict research activities and reduce the chances for technological improvement;
6. may restrict the amount of reimbursement or disallow reimbursement for special methods of transporting kidneys;
7. severely limit the ability of the effected agencies to acquire funding from other sources;
8. would interfere with non-renal business activities of the agencies and laboratories;
9. would generally dictate allowable costs and the extent of the allowance of those costs.

In addition to the concern that the cost reimbursement policy may adversely effect the number of kidney transplants, there is an additional concern. This concern is related to the fact that the regulations for reimbursement of O.P.A.'s and laboratories were issued on December 14, 1978, and to date no one seems to know exactly how the reimbursement mechanism will be formulated or implemented. Included in this is the possibility that when policies are finally developed, such regulations may be retroactive. This could prove financially devastating to many of the O.P.A.'s and laboratories. It is the feeling of the Midwest Organ Bank that these concerns illustrate the disincentives to the O.P.A.'s and laboratories to either stay in business or expand their existing programs. Ultimately, such disincentives will result in fewer available kidneys for transplantation.

The Midwest Organ Bank provides its services in a two-state area of Kansas and Western Missouri. Its function is to provide cadaveric transplants and tissue typing for patients throughout this area. It is important to point out the positive effect that such agencies as the Midwest Organ Bank has to the transplant program regionally as well as to the nation on a whole. In 1979, the Midwest Organ Bank supplied the equivalent of 120 kidneys with its organ retrieval efforts. The agency supplied the equivalent of 6% of the kidneys used for cadaveric transplants in the United States. This figure is significant in light of the fact that the region contains only 3% of the Medicare population. Furthermore, it should be noted that the independent agencies as a whole retrieve approximately 45% of all cadaveric kidneys used in transplantation.

III. POSITION

The position of the Midwest Organ Bank is primarily based upon the relationship between the federal government and the independent O.P.A.'s and laboratories. What the Midwest Organ Bank proposes to seek on behalf of all independent agencies and laboratories is an emphasis on the "independent status" of such organizations. Instead of the use of a massive regulatory scheme incompatible with such organizations, the return to a contractual relationship would appear more viable. Similar to the reimbursement mechanism utilized prior to the passage of Public Law 95-292, the Midwest Organ Bank contends that cost containment can be realized through an annual prospective budget negotiation process. It should be noted that Congress was not necessarily dissatisfied with the previous program, but only with the rising costs associated with transplantation.

The real issue then is whether Congress comprehended the type of reimbursement mechanism and regulations installed in association with this legislation. If so, the inten to increase the number of transplants for dialyzed patients will either stagnate or decrease. The Midwest Organ Bank supports and encourages cost effectiveness within its own operation and recognizes that this is a chief concern of Congress. However, other alternatives in the implementation of the legislation should be explored.

ity), transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode if payments for his other professional services furnished to an individual who has end-stage renal disease are made on the basis specified in paragraph (3)(A) of this subsection, and (B) payments to or on behalf of such individuals for home dialysis supplies and equipment. The requirements prescribed by the Secretary under subparagraph (A) shall include requirements for a minimum utilization rate for covered procedures and for self-dialysis training programs.

"(2)(A) With respect to payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals determined to have end-stage renal disease for which payments may be made under part B of this title, such payments (unless otherwise provided in this section) shall be equal to 80 percent of the amounts determined in accordance with subparagraph (B); and with respect to payments for services for which payments may be made under part A of this title, the amounts of such payments (which amounts shall not exceed, in respect to costs in procuring organs attributable to payments made to an organ procurement agency or histocompatibility laboratory, the costs incurred by that agency or laboratory) shall be determined in accordance with section 1861(v). Payments shall be made to a renal dialysis facility only if it agrees to accept such payments as payment in full for covered services, except for payment by the individual of 20 percent of the estimated amounts for such services calculated on the basis established by the Secretary under subparagraph (B) and the deductible amount imposed by section 1833(b).

42 USC 1395j.

42 USC 1395.

42 USC 1395x.

42 USC 1395*l*.

Regulations.

"(B) The Secretary shall prescribe in regulations any methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end-stage renal disease, and (ii) determine, on a cost-related basis or other economical and equitable basis (including any basis authorized under section 1861(v)), the amounts of payments to be made for part B services furnished by such providers and facilities to such individuals. Such regulations shall provide for the implementation of appropriate incentives for encouraging more efficient and effective delivery of services (consistent with quality care), and shall include, to the extent determined feasible by the Secretary, a system for classifying comparable providers and facilities, and prospectively set rates or target rates with arrangements for sharing such reductions in costs as may be attributable to more efficient and effective delivery of services.

"(C) Such regulations, in the case of services furnished by proprietary providers and facilities may include, if the Secretary finds it feasible and appropriate, provision for recognition of a reasonable rate of return on equity capital, providing such rate of return does not exceed the rate of return stipulated in section 1861(v)(1)(B).

"(D) For purposes of section 1878, a renal dialysis facility shall be treated as a provider of services.

42 USC 1395oo.

"(3) With respect to payments for physicians' services furnished to individuals determined to have end-stage renal disease, the Secretary shall pay 80 percent of the amounts calculated for such services—

"(A) on a reasonable charge basis (but may, in such case, make payment on the basis of the prevailing charges of other physicians for comparable services) except that payment may not be made under this subparagraph for routine services furnished during a maintenance dialysis episode, or